PROMPPT Training Manual

Manual to complement the PROMPPT e-learning platform and group learning sessions

October 2020

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Module 1: PROMPPT Foundation Course

1.1 Introduction to the PROMPPT Training

(See also: E-learning course- Introduction)

The PROMPPT Training package has been prepared by clinicians and researchers involved in the PROMPPT research programme and aims to support clinical pharmacists in general practice to deliver pain management reviews to patients prescribed long-term opioids for persistent pain as part of the PROMPPT research programme. This manual is designed to be used in conjunction with the other components of the PROMPPT training package as outlined below.

1.1.1 The PROMPPT Training Package

The PROMPPT training package comprises:

The PROMPPT Training Manual (this manual)

- PROMPPT Feasibility study: An Executive Summary is also available covering the key points

The PROMPPT e-learning course

1. PROMPPT Foundation Module

   The Foundation Module covers important background knowledge regarding persistent pain, opioids and the PROMPPT research programme.

2. Consultations Skills Module

   The Consultation Skills module covers the skills needed to conduct effective pain management consultations, promote behaviour change in relation to opioid use and agree a management plan.

3. Pain Management Skills Module

   The Pain Management Skills module covers topics relating to the delivery of the management plan including management of opioids and non-opioid pain medicines, supporting patient self-care for persistent pain, collaboration with GPs and others, patient information resources signposting and referrals.

4. PROMPPT Resource Library

   Links to all documents used in delivering the PROMPPT Pain Management Review and links to supplementary training resources are located in the Resource Library **(training manual section 4, *PROMPPT Resources Library*)** and on the e-learning platform: PROMPPT Resource Library.

In-practice homework assignments

- Assignment 1

        - Practice active listening with patients talking about pain and try using the Pain Concerns Form in practice. Reflect on what went well and what didn't go so well and note any questions you have.
        - To be completed in advance of Group Learning Session 1
    - Assignment 2
        - Practice using motivational interviewing techniques with chronic pain patients & reflect on experiences of discussing self-care with patients
        - To be completed in advance of Group Learning Session 2

Group learning sessions

- Group Learning Session 1
    - Feedback and discussion about experiences of listening to patients talk about pain and using the Pain Concern Form
    - Role play relating to active listening
    - Role play of exploring pain more widely using Pain Concerns form
    - Discuss homework assignment 2 – relating to motivational interviewing and discussions around self-care for chronic pain
- Group Learning Session 2
    - Discussion of experiences of using motivational interviewing techniques and of discussing self-care with chronic pain patients.
    - Role play relating to Motivational Interviewing skills
    - Role play relating to self-care conversations

1.1.2 Intended learning outcomes

PROMPPT Foundation Module

As a result of completing the PROMPPT Foundation Module, participants should

- Have a better understanding of persistent pain and the role of self-care in managing patients with persistent pain.
- Understand the rationale for the PROMPPT research based on UK trends in opioid prescribing and the effectiveness and risks of opioids for persistent pain
- Understand their role in the PROMPPT Feasibility Study

Consultations Skills Module

As a result of completing the Consultations Skills Module, participants should feel better equipped and more confident to:

- Conduct consultations with patients with persistent pain
- Explore the impact of persistent pain on patients' lives
- Explore the effects (wanted and unwanted) of opioids prescribed for persistent pain
- Understand the patient's perspective on opioids and their readiness to make changes to their opioid medicines
- Explore ambivalence to changing opioids
- Explain persistent pain and the issues around opioid therapy, incorporating patients' health beliefs and best practice guidance
- Discuss the role of self-care for persistent pain
- Negotiating management plans with patients and shared decision making

Pain Management Skills Module

As a result of completing the Pain Management Skills Module, participants should feel better equipped and more confident to create a PROMPPT review plan including:

- An opioid tapering plan, where appropriate
- Advice on optimising non-opioid pain medicines, where appropriate
- Supporting patient self-care for persistent pain, including SMART goal setting
- Signposting patients to relevant information resources
- Understanding when to seek help / collaboration from the GP and when / how to signpost or refer to other services

1.1.3 PROMPPT study contacts

Study management is by Keele Clinical Trials Unit (CTU)

sch-tr.studypromppt@nhs.net

If you have any problems or require more information about PROMPPT, please contact the study team on the email address above and you will be directed to the most appropriate person to deal with your enquiry.

You will also be supported through the study period by a PROMPPT Clinical Champion. The Clinical Champions will be your first point of contact with clinical questions relating to the PROMPPT pain management reviews. More information about the clinical champions is available via the e-Learning.

1.2 Background: Opioids for patients with persistent pain

(See also: E-learning course- PROMPPT Foundation Module, Opioids for patients with persistent pain: some background)

1.2.1 Persistent pain and the role of self-management

The PROMPPT research programme aims to improve care for patients living with persistent pain. To achieve this aim it is important for pharmacists to have a broad understanding of what pain is and what we mean by persistent pain. This lesson outlines what pain is, what we mean by persistent pain and why it is important to consider the psychology of pain. The lesson finishes with an outline of self-care strategies that can be useful for people living with pain.

Persistent pain

Pain is normal. Pain is protective and there is sometimes a clear reason for having it, for example following a sprained ankle or a pin-prick. The perception of pain at any one time depends in part on the individual patient's previous experiences, the context and their mood at that time. The term nociception (and nociceptive pain) is used to describe pain in a normal functioning nervous system. Not all activity in the nociceptive system results in pain, because the noxious stimuli has to be perceived psychologically to be painful.

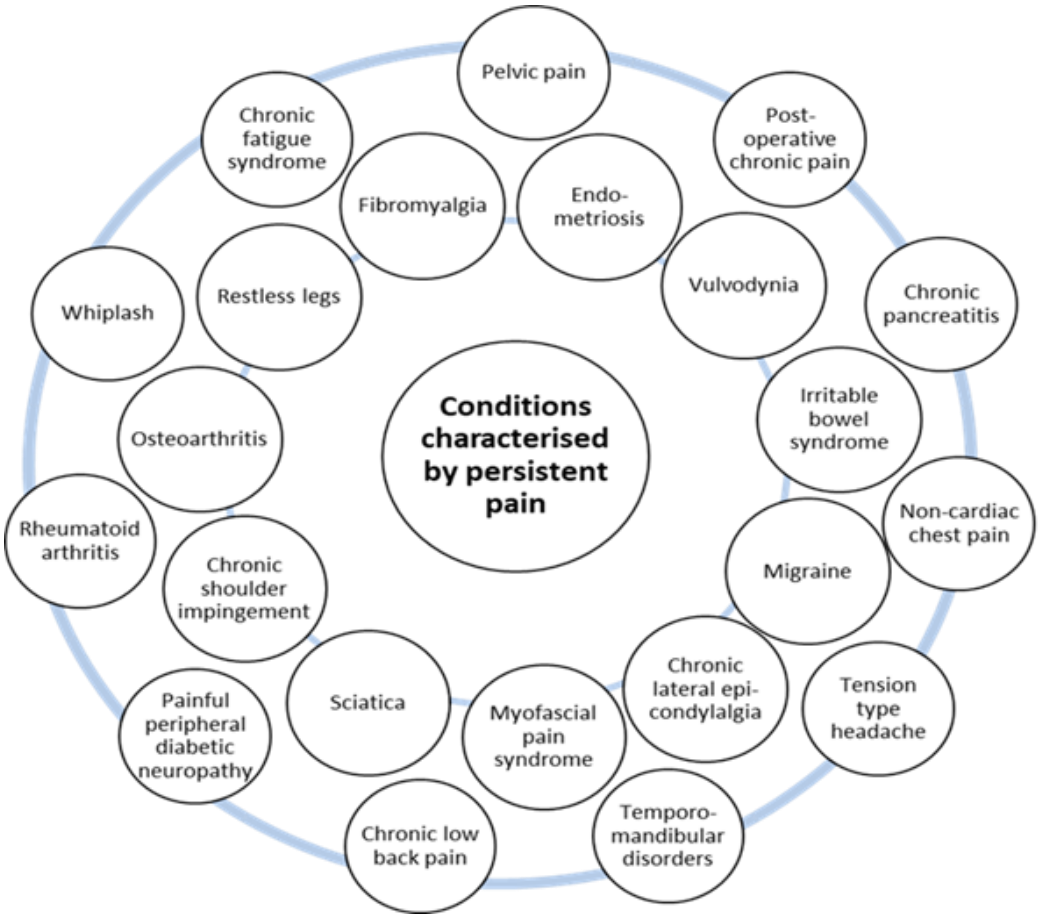
Persistent pain (otherwise known as chronic pain) is different to nociceptive pain (or acute pain). Often the reason for persistent pain is less clear than for acute pain, other differences between the two are summarised in table 1.1 It is important to note that it is not always clear whether a patient consulting with pain has acute or persistent pain, the reality in clinical practice is far muddier than on paper.

Table 1.1 Summary of differences between acute pain and persistent pain conditions

Acute pain	Persistent pain
Likely to have recent onset, such as related to an injury or acute illness (for example pin prick, or sprained ankle)	Likely to have long duration (3 months or longer) and persist beyond expected tissue healing
Often localised to the area of injury	Widespread pain, unpredictable
Aggravating and easing factors are often clear	Pain often easily irritated and aggravating factors not clear
Responds well to simple analgesia and other treatments (for example, Physiotherapy)	Difficult to reduce, or control even when using regular pain medicines.

Persistent pain is characterised by pain sensitisation. Pain sensitisation is the amplification of pain caused by changes in the spinal cord and higher centres of the brain that cause an increased sensitivity of neurons in the central nervous system. Often the reasons for persistent pain are not clear, but there are a number of pain conditions that are known to be associated with pain sensitisation, Figure 1.1 highlights some of these conditions. Clinicians in every medical speciality will see patients with persistent pain and despite differences, the underlying pathophysiological mechanisms for pain sensitisation is common across them all.

Figure 1.1. Conditions characterised by persistent pain. Adapted from (Arendt-Nielson, et al., 2018).



Psychology and pain

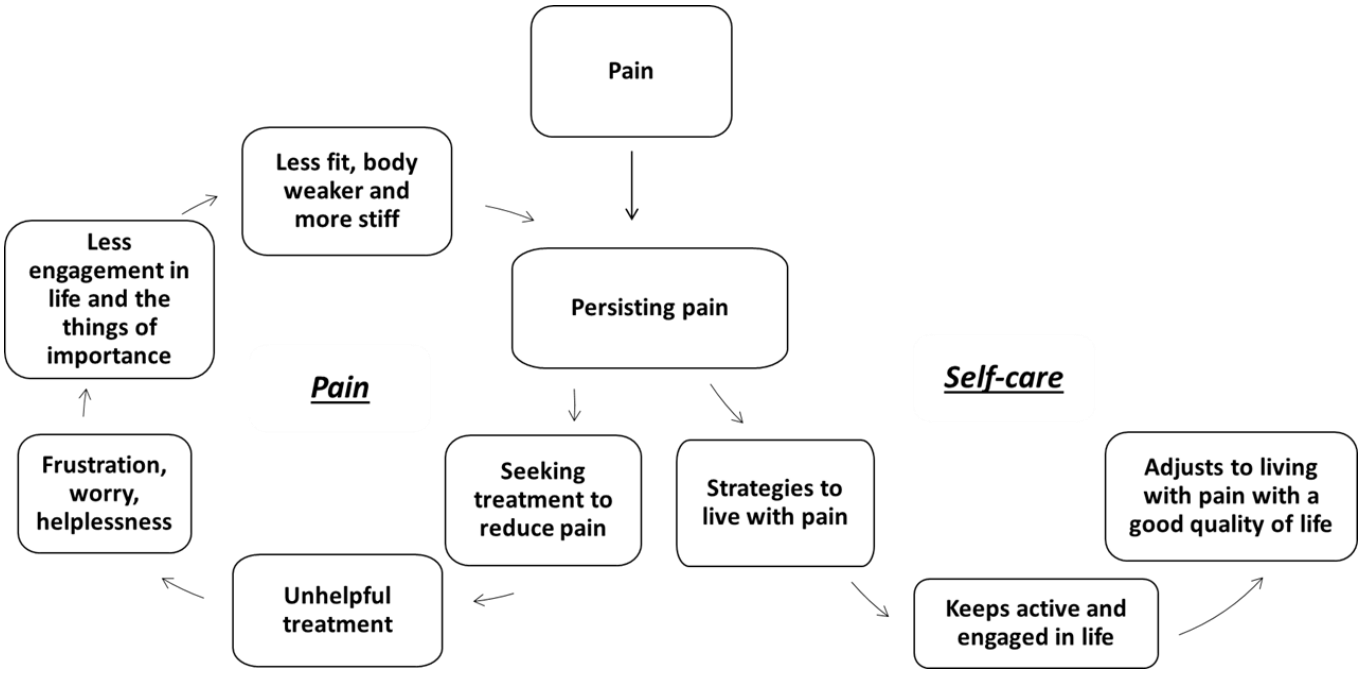
Persistent pain can affect all areas of life and this contributes to the overall pain experience (see figure 1.2). Mood and psychology are always important to consider, even if biological or social causes seem to predominate. Many people living with persistent pain describe their mood as low. They often report feeling helplessness directly about their pain, loss about the things they can't do and worries about their future. This can be different to clinical depression where symptoms such as worthlessness and low self-esteem may be more problematic. When patients feel low or anxious, pain can be more distressing and harder to live with.

Figure 1.2 The wider aspects of pain that can contribute to an overall pain experience.

In a consultation with someone who has pain, it is difficult to avoid the psychology of it but the temptation is often to duck out of talking about it. In people with pain, it is often psychological factors, such as anxiety and depression, that predict whether patients consulting with pain move on to having persistent pain (Pincus & McCracken, 2013).

The psychology of pain partly explains why it is difficult to control, or reduce persistent pain using pharmacological treatment or by using treatments such as injections. For these reasons, in patients with persistent pain, pain relief is typically not the primary aim of treatment (The British Pain Society , 2013) and the focus instead is on an improvement in activity, mood and quality of life *with* pain.

Figure 1.3 The cycle of pain versus self-care. Adapted from (Vlaeyen & Linton, 2000).



As human beings, we naturally tend to avoid or control pain. There is nothing wrong with this when it works, but in the long-term, continuing unsuccessful control strategies can make matters worse rather than better. This is sometimes known as the pain cycle (see figure 1.3). Self-care strategies to help the patient adjust to living with pain, rather than avoiding pain are important because it brings opportunities to improve quality of life by enabling patients to better manage the impact of pain on everyday life (Unruh & Harman, 2007). Comparing the self-care cycle with the pain cycle, many patients will recognise that this looks a better way forward, even if they can't quite see how to apply it to their own situation.

Self-care strategies for pain

Applying self-care strategies requires the patient to have some acceptance of their circumstances and of their pain (Kallhed & Martensson, 2018). Patients often develop their own strategies to help them manage activities of daily living and examples include; performing activities in different ways, distraction from pain, planning, avoiding and prioritising tasks (Kallhed & Martensson, 2018). Some strategies are more helpful than others and having a number of self-care strategies is often more useful than having one or two.

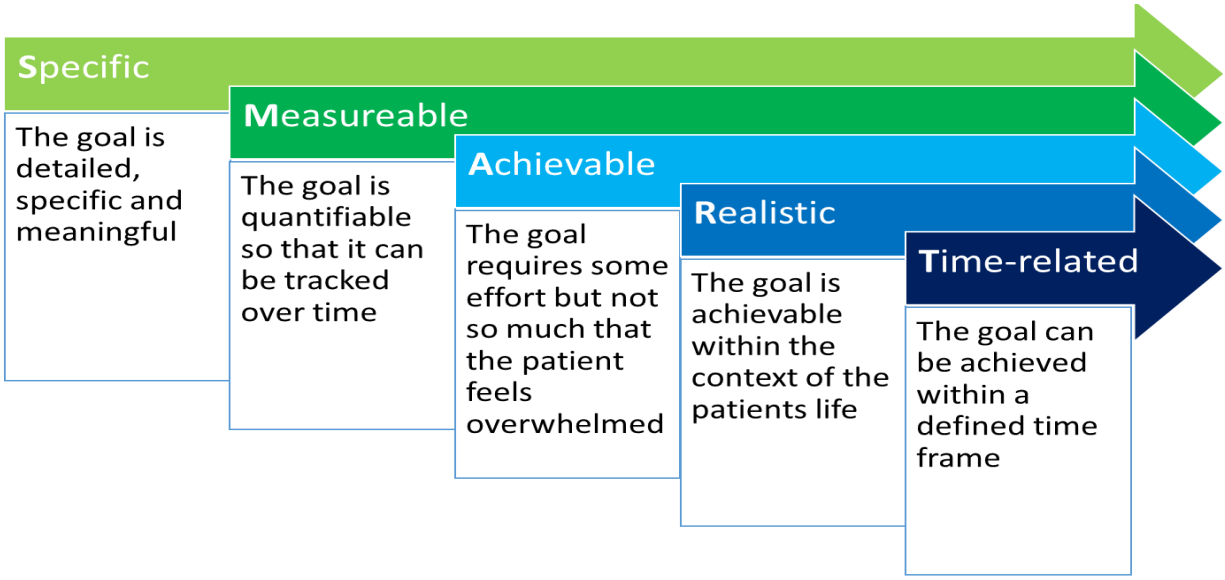
This section outlines three strategies (pacing, getting active and set-back planning) that could help patients live with pain and achieve a good quality of life. Later on in the training we outline how to listen out for evidence of self-care strategies and some tips for snippets of advice that could help patients live well with pain **(training manual sections 3.2, *Supporting self-care strategies* and 3.3, *Pain review plan & self-care information*).**

Goal setting and action planning

Goal setting can be useful to help patients take action once they have agreed to make changes to the medicines they regularly take. There are two components implicated within a goal, that of identifying a goal and an action plan, which is the effort that an individual patient makes in order to achieve it. Setting goals can be a useful way of communicating with patients and other members of the healthcare team within primary care (Levack, et al., 2016). Involving patients in some form of structured goal setting is likely to increase compliance, motivation and other factors such as pain self-efficacy (Levack, et al., 2016) (Wade, 2009) (Rose, et al., 2017).

SMART is a commonly used acronym to guide goal setting, see figure 1.4 for a summary of the SMART acronym. In some circumstances SMART goals have been replaced by SMARTER goals, where E can stand for evaluated and R is often associated with the words reviewed or rewarded (Wade, 2009).

Figure 1.4 SMART goals: using commonly used words for each letter of the acronym



It is useful to support patients to identify goals that help them move towards something that is of importance to them and the kind of person that they want to be. This means that the goal may help them to move towards caring for or spending time with family, or financial stability for example, these goals are values-based. Other aspects that are important to consider in goal-setting is the support available to the patient and the time period over which (or date when) the identified goal is to be achieved (Bovend'Eerdt, et al., 2009).

We will revisit goal setting later in the manual **(training manual section 3.2.1, *Goal setting and action planning*)**, where we will discuss *how* to set SMART patient goals.

Pacing

How patients go about their daily activities can be unhelpful, being either overactive, underactive or alternating between the two in a “boom and bust” cycle. Helpful pacing is a strategy to help patients remain active without flaring up pain unnecessarily. The concept of helpful pacing ties in nicely with goal setting whereby there may be scope for patients to pace the duration, speed and, or distance of their activities with the aim of progressing towards a values-based goal.

Getting active

It is often important for people living with pain to be more active but pain makes it more difficult to engage with and to continue with regular physical activity. The benefits are numerous, and regular physical activity is likely to help with many of the wider aspects of pain such as mood problems and sleep disturbance. When patients have agreed to a reduction in pain medicines regular exercise can be a good distraction.

Patients often ask which type of exercise is the best for their pain but there is no one form of exercise that is better than all others. There has been a shift away from prescribed activity, for example arm exercises x10, 4-times daily as this could reinforce that being active is a short term thing. A better approach is for patients to increase the regular physical activity within the activities that help them move towards their values.

1.2.2 Rise in opioid prescribing

Opioid prescribing for persistent pain has increased dramatically since the 1990’s. There has been a trend towards prescribing stronger long-acting opioids and earlier escalation from ‘weak’ (e.g. codeine) to ‘strong’ opioids (e.g. morphine) (Bedson, et al., 2016).

Between 1998 and 2016 (Curtis, et al., 2019):

- Opioid prescriptions in England increased by 34% overall & by 127% after adjusting for morphine equivalence
- The number of **high dose** (> 120mg morphine equivalent dose(MED)) prescriptions increased by 581% from 3 to 23 per 1000 population.
- Fentanyl, morphine, and oxycodone, together accounted for more than 90% of high dose long-acting opioid prescribing in 2016. Oxycodone prescribing having increased the most since becoming available in 2000.
- There is considerable variation in opioid prescribing between different CCGs across England with a 6-fold variation in the number of opioid items prescribed and an 8-fold variation in MED per 1000 patients.
- Higher levels of GP practice-level opioid prescribing have been associated with larger practice size, more rural location and higher deprivation score.

- If every practice in the country prescribed high-dose opioids at the same rate as those in the lowest 10% it has been estimated that, over a 6-month period, 543 000 fewer high dose prescriptions could have been issued (from a total of 601 000) with a cost saving of £24·8 million.
- There is some evidence to suggest a slowing of the rising trend in opioid prescribing, but this is not consistent between geographical areas.
- Overall opioid prescribing in England started to plateau around 2014 and there was an overall slight decline between 2016-2017.
- However, beneath this trend lies a wide variation and the change in total opioid prescribing between 2016-2017 across CCGs in England ranged from a 10.5% decrease to a 3.5% increase

OpenPrescribing.net is a useful tool that's provide a current picture of opioid prescribing (Curtis & Goldacre, 2017). You can find out how opioid prescribing in your practice compares to national averages by visiting openprescribing.net it's free to access. You'll get graphs showing total opioid prescribing (morphine equivalent) per 1000 registered patients and you can also find out what proportion of this is high dose prescribing.

1.2.3 Effectiveness and risks of long-term opioid therapy for persistent pain

Effectiveness of opioids

Evidence for long-term effectiveness of opioids for people with persistent pain is limited (Furlan, et al., 2006) (Nobles, et al., 2008) (Hauser, et al., 2015). Although opioids are effective analgesics for acute pain and pain at the end of life, the majority of people living with persistent pain do not obtain useful pain relief from opioids (Moore, et al., 2013).

In fact, people with persistent pain who take opioids are more likely to report worse pain, poorer self-rated health, and lower quality of life than people with persistent pain who do not take opioids (Erikson, et al., 2011) (Jenson, et al., 2006). These data suggest that, for many people with persistent pain, opioid therapy does not fulfil the key goals of treatment, namely pain relief, improved functioning and improved quality of life

Risks of long-term opioid therapy

At the same time, opioid therapy is frequently associated with side-effects that may worsen quality of life, including constipation, nausea, dizziness, sedation and confusion (Furlan, et al., 2006) (Nobles, et al., 2008) (Annemans, 2011) and with an increased risk of serious harm including overdose, addiction, fractures and myocardial infarction (Gordon, et al., 2017) (Chou, et al., 2015) (Primary Care Commissioning , 2019).

Patients taking opioids long-term for persistent pain are therefore at risk of continuing medicines that may be harming more than helping them.

Opioid misuse and addiction

The terminology around problematic prescribed opioid use, including misuse and addiction, is confusing and often used inconsistently, so it seems useful to begin by being clear about definitions:

Physical dependence

Physical dependence occurs due to biological changes associated with repeated use of opioids leading to tolerance (less effect from a given amount or dose) and withdrawal symptoms if the substance is rapidly reduced or stopped abruptly.

- Physical dependence on opioids is highly likely in patients who have been taking prescribed opioids regularly
- The likelihood of physical dependence is why regular opioids should be tapered gradually before stopping, in order to avoid withdrawal symptoms
- Physical dependence alone does not mean that patients misuse or are addicted to opioids.

Psychological dependence

Psychological dependence is the when use of a drug is a conditioned response to an event or feeling (known as a "trigger"). Triggers can be emotional responses to events, certain people, places or anything a person associates with using the drug.

- The presence of physical and psychological dependence makes addiction likely but isn't the whole story because addiction also has a behavioural component.

Misuse

Prescribed opioid misuse refers to the use of prescribed opioids in a way that is not consistent with what has been directed or prescribed, regardless of whether they cause harm or not. Misuse can lead to addiction but that is not always the case and they are not the same thing.

Abuse

Prescribed opioid abuse is the intentional use of a prescribed opioid for a nonmedical purpose, such as euphoria or altering one's state of consciousness.

Addiction

The main characteristic that distinguishes addiction is the combination of psychological and physical dependence with compulsive behaviour that leads to a pattern of continued use regardless of the harm the drug (opioids) causes or may cause to themselves or others.

Opioid use disorder

This term may be used to encompass the spectrum of misuse, abuse and addiction.

It has been estimated that opioid addiction occurs in around 8-12% of patients prescribed opioids for persistent pain and misuse in up to 30%. Addiction is an important risk and often the one that grabs the headlines but it is important to remember that the majority of patients who use opioids for persistent pain do not become addicted to them. Labelling patients inappropriately as 'addicted' to opioids when they are in fact simply displaying signs of physical dependence has the potential to adversely affect patient care and the clinician-patient relationship.

1.2.4 Best practice guidance on managing opioid therapy for persistent pain

Best practice guidelines (Faculty of Pain Medicine, 2015) (Dowell, et al., 2016) (O'Brien, et al., 2017) recommend using non-opioid management strategies, where possible, for persistent pain. Where opioids are prescribed for persistent pain, an opioid trial is recommended, with clear agreed goals for treatment (Faculty of Pain Medicine, 2015) (Dowell, et al., 2016) (O'Brien, et al., 2017). Patients should be reviewed within 4-6 weeks to assess their response in relation to treatment goals. Patients who do not achieve useful pain relief from opioids within 2-4 weeks are unlikely to gain benefit in the long term and continuing opioids in these patients is not recommended. For patients who obtain benefit in the short-term, this does not guarantee long-term efficacy and regular review is recommended, at least 6 monthly, to assess whether benefits continue to outweigh any adverse effects and potential harm. However, implementation of opioid guideline recommendations is low (Krebs, et al., 2014) (Starrels, et al., 2011). Lack of time and resources are potential barriers to guideline-concordant care (Krebs, et al., 2014) (Starrels, et al., 2011) and the available time in routine GP appointments offers limited opportunity to undertake a comprehensive face-to-face review.

Tapering and stopping opioids is recommended if treatment goals are not met, even when there are no alternative analgesics (Faculty of Pain Medicine, 2015). Studies of gradual reduction of long-term opioids in the context of multidisciplinary pain management programmes report that, overall, patients do not experience worse pain and may notice improved function and quality of life (Berna, et al., 2015). It seems that opioids are prescribed more often and for longer than would be expected given the evidence for their effectiveness for persistent pain (Moore, et al., 2013) (Stannard & Johnson, 2003).

1.3 Introduction to the PROMPPT research programme

(See also: E-learning course- PROMPPT Foundation Module, An introduction to the PROMPPT research programme)

1.3.1 Rationale for PROMPPT

In light of the lack of evidence supporting the effectiveness of opioids and concerns about the potential harms, best practice guidelines (Dowell, et al., 2016) (Faculty of Pain Medicine, 2015) (O'Brien, et al., 2017) recommend that opioids should be reviewed within 4 weeks of starting opioid treatment, at least 6 monthly once a stable dose is reached, and more often if there are concerns. Structured review is recommended, taking into account evidence of

effectiveness, including functional improvement / progress towards treatment goals, side-effects and evidence of problematic use (Berna, et al., 2015). Supporting patients to taper and stop opioids is recommended if treatment goals are not met (Dowell, et al., 2016) (Faculty of Pain Medicine, 2015) (O'Brien, et al., 2017).

In practice, implementation of these opioid guideline recommendations is low (Krebs, et al., 2014) (Starrels, et al., 2011). Lack of time is an important barrier and the available time in routine GP appointments offers limited opportunity to undertake a comprehensive review. The expansion in the clinical pharmacist workforce in UK primary care (NHS England, 2017) (NHS England, 2017) presents an opportunity to address this. One emerging role for clinical practice pharmacists is reviewing patients with polypharmacy and complex medicines regimens. Given that increasing polypharmacy is associated with incremental increases in long-term and stronger opioid prescribing (Foy, et al., 2016), practice pharmacists seem ideally placed to take a proactive role in reviewing and managing patients on long-term opioids. Currently, however, there is no evidence about how they should do this or whether it would be clinically or cost-effective. The PROMPPT programme aims to fill this evidence gap.

1.3.2 Aim of PROMPPT

The PROMPPT research programme aims to develop and test a clinical pharmacist-led primary care intervention (PROMPPT) to reduce opioid use for people with persistent pain (where appropriate) and support self-management for those with persistent pain in primary care.

1.3.3 Research plan

PROMPPT is a 5-year research programme comprising three linked workstreams.

Workstream 1

In workstream 1 we combined findings from 4 qualitative studies with best practice guidance and theory to co-design the PROMPPT pain management review and clinical pharmacist training package with a range of stakeholders including patients, clinical pharmacists, GPs and healthcare professionals with pain management expertise.

Workstream 2

We are now in workstream 2, a non-randomised feasibility study which will inform refinement of the PROMPPT pain management review and training package as well as the design of the proposed main trial design.

4 practice pharmacists in 4 different GP practices (2 East Midlands, 2 West Midlands region) will take part in the feasibility study, which aims to recruit 80 patients across the 4 practices.

The overall aim of this study is to investigate the credibility and acceptability (to patients, clinical pharmacists and GPs) of PROMPPT, the practicality of clinical pharmacists delivering PROMPPT in primary care and the effectiveness of the training package in

enabling clinical pharmacists to deliver the PROMPPT intervention to patients prescribed long-term opioids for persistent pain in primary care. We will also explore the feasibility of the proposed design for a main trial to test clinical and cost-effectiveness.

Workstream 3

In workstream 3 a large multicentre cluster randomised controlled trial (cluster RCT) will test the clinical and cost-effectiveness of providing the PROMPPT pain management review. This trial will investigate whether, compared with usual care, providing a PROMPPT pain management review for patients prescribed long-term opioids for persistent pain reduces opioid use (by at least 25% on average), without making pain/pain-related interference worse. We will use mean daily morphine equivalent dose (MED) to measure opioid use.

1.3.4 PROMPPT patient selection criteria

Potentially eligible patients will be identified by screening electronic practice records

Inclusions

Patients are eligible to take part if they are:

- Adults aged ≥18 years
- Prescribed any opioid-containing analgesic for persistent non-cancer pain continuously for ≥6 months, with a prescription issued within the previous 2 months.

Exclusions

GPs will be asked to screen the lists of patients identified to exclude:

(1) Patients with acute pain, cancer pain and/or terminal illness (life expectancy <6m);

(2) Vulnerable patients (e.g. severe mental illness, learning difficulties, dementia);

(3) Patients currently receiving treatment for substance misuse;

(4) Patients who are unable to understand English.

1.3.5 Objectives of the PROMPPT pain management review

PROMPPT aims to reduce opioid use for people with persistent pain *where appropriate*.

It may not be appropriate for all patients to reduce opioids and some patients may not yet be ready to reduce their opioids. So it is important to recognise **all** the potentially useful outcomes from an individual PROMPPT pain management review.

Examples of 'successful' outcomes of PROMPPT pain reviews :

● The patient successfully reduces or stops opioids - this is the 'ideal outcome' where opioid reduction is appropriate.

● Opioids stay the same because benefits outweigh harms/risks (e.g. low dose / intermittent with evident functional benefit) AND the patient is now aware of the potential risks of opioids, the role of self-care in managing persistent pain and understands why it's important to

review opioid use. There may also be scope to reduce ineffective / potentially harmful non-opioid pain medicines.

● Opioids stay the same because the patient does not feel ready to try reducing opioids BUT is now aware of the potential risks of opioids, the role of self-care in managing persistent pain and understands why it's important to review opioid use. This may 'sow a seed', leading to the patient reflecting on their opioid use / pain management strategies and they may consider making a change in future. There may also be scope to reduce ineffective / potentially harmful non-opioid pain medicines.

● Opioids stay the same even though the patient wanted to escalate, potentially harmful escalation has been avoided AND the patient is aware of the potential risks of opioids, the role of self-care in managing persistent pain and may be less likely to escalate or request escalation of their opioids in future. As above this may 'sow a seed', leading to the patient reflecting on their opioid use / pain management strategies and they may consider making a change in future. There may also be scope to reduce ineffective / potentially harmful non-opioid pain medicines.

1.4 The PROMPPT pain management review

(See also: E-learning course- PROMPPT Foundation Module, An introduction to the PROMMPT pain management review)

PROMPPT is a clinical pharmacist-led intervention incorporating proactive review for patients who have been taking opioids regularly for at least 6 months and aims to reduce opioids, where appropriate, and to support self-management of persistent pain.

1.4.1 Pre-consultation information

Patients will be invited to arrange an appointment for a PROMPPT pain management review with the clinical pharmacist working at their practice. The patient invitation letter will be accompanied by a Pain Concerns Form **(training manual section 4.2, *Pain Concerns Form*).**

Pain Concerns Form

The PROMPPT Pain Concerns Form and the Pain Navigator Tool (Bloomkvist & Bell, 2018) (Pain Concern, n.d.) from which it was derived, were developed to allow patients to raise concerns about the wider issues of living with pain that they might not always feel is relevant to raise in a consultation about their opioid medicines.

Specifically, the Pain Concerns Form was designed, in conjunction with patients and other stakeholders, to help focus the consultation on the things that are most important to the patient. The Pain Concerns Form comprises a list of statements in four sections (see bullet points below) that represent concerns about pain, the impact of pain on everyday life and pain medicines that are commonly reported by patients with persistent pain.

- The first section “About my pain” covers some of the concerns patients have about their pain diagnosis, prognosis and treatment of their condition.
- The changes to the patient’s life and the way they are feeling are covered in the second section “Because of my pain…”
- Treatment concerns and specifically about medicines are covered in the penultimate section “Regarding the medicines I take for my pain”.
- In the final section of the form, there is a free-text box for additional concerns related to their pain or the management of their condition.

Training manual section 2.2, *Using the Pain Concerns form to explore persistent pain more widely* will outline how to use the form within your consultation.

1.4.2 PROMPPT initial consultation

It is advised that 30 minutes is scheduled for the first PROMPPT consultation (not including time to complete study documentation). This consultation may be conducted face-to-face or remotely by video or telephone, depending on the impact of COVID-19 on service provision and any ongoing social distancing measures.

The initial consultation includes assessment of the patient’s perspective regarding their pain and its management and the impact of pain on their life. Followed by a personalised discussion to explore the patient’s experience and perspective on the effects (wanted/unwanted, useful/bothersome) of opioids.

Motivational interviewing techniques will be used to explore patient’s reasons for considering changing their opioid medicines, their readiness to change and any ambivalence, before agreeing an individualised management plan. Management plans will arise from shared decision making. The plan may include opioid tapering but this will not be mandatory, for example if the patient obtains continued useful benefit from moderate dose opioids, without experiencing troublesome side-effects.

Where changes to medicines are agreed, SMART (specific, measurable, achievable, realistic, time-related) goal setting will be used to facilitate translation of intentions into action. Important barriers to reducing opioids, for example fear of pain worsening and/or withdrawal symptoms following opioid reduction, will be addressed on an individual basis.

Management plans may also include advice and goals relating to self-management, signposting to information resources, signposting or referral to appropriate community services (for example physiotherapy, exercise classes and community psychology services) and, for more complex cases, discussion/collaboration with the GP and/or referral to specialist services if needed.

All the components of the PROMPPT consultation and the skills you will need will be covered in more detail in **training manual module 2, *PROMPPT Consultation Skills* and module 3, *PROMPPT Pain Management Skills*** and in the corresponding E-learning modules.

1.4.3 Follow-up

Follow-up appointments will be arranged according to clinical need and may be conducted face-to-face or remotely by video or telephone, according to the need for social distancing and patient preference. Follow-up appointments are anticipated to be shorter in duration (no longer than 15 minutes).

Arrangements for contact outside of appointments will be agreed, for example, patients may leave a message at reception and the clinical pharmacist will ring the patient back or if systems allow and the answer is simple, the pharmacist may text the patient back. Follow-up will be looked at in more detail in **training manual section 3.5.1, *Follow-up*.**

1.5 Taking part in the PROMPPT feasibility study

(See also: E-learning course- PROMPPT Foundation Module, The PROMPPT feasibility study)

1.5.1 The feasibility study: three studies in one.

The PROMPPT feasibility study primarily consists of three components:

1. A Questionnaire study

   An invitation pack will be sent to eligible patients by the GP practice inviting them to take part in the PROMPPT feasibility study. Once a consent to contact form is received by Keele Clinical Trials Unit (CTU) a baseline questionnaire will be mailed to the patient to complete. A follow-up questionnaire will also be sent to the patient 3 months after Keele CTU receive the completed baseline questionnaire. The patient facing name of this part of the study is MOPP (Management of Opioids & Persistent Pain).

2. PROMPPT Pain review consultation

   Upon receiving a completed baseline questionnaire, Keele CTU will send an invitation letter (on GP letter headed paper) to the patient inviting them to attend a pain management review. The patient will contact the GP practice to schedule the pain review with the clinical pharmacist. Although the PROMPPT pain review consultation forms part of the feasibility study and patients are aware of the practices' involvement in the research study, the pain review should be seen as standard clinical care provided to the patient by their GP practice.

3. Process Evaluation

   A sample of pain reviews (n=2 per practice) will be observed and/or audio-recorded with prior consent from both the patient and clinical pharmacist.

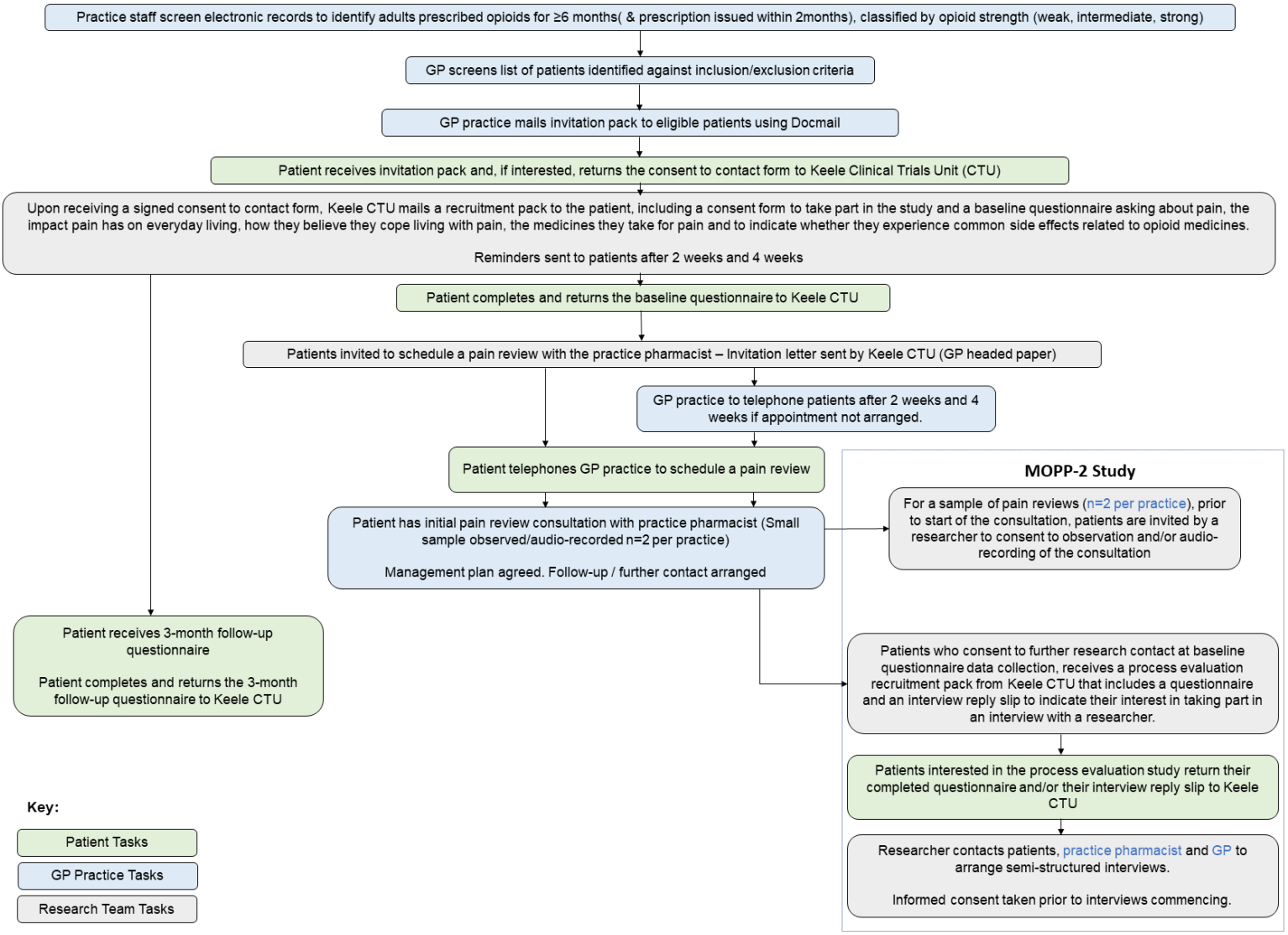
   Patients who attend a pain review consultation and who consented to further research contact during the baseline questionnaire data collection, will receive a process

evaluation pack from Keele CTU inviting them to complete an acceptability questionnaire and/or take part in a semi-structured interview with a researcher. The clinical pharmacist and GP lead for the study will also be interviewed once many of the pain review consultations have taken place. The patient facing name of this part of the study is MOPP-2

1.5.2 The study flow chart

The below study flow chart outlines the PROMPPT feasibility study process.

Figure 1.5 PROMPPT feasibility study flowchart



1.5.3 Involving the whole practice

The study flow chart highlights the involvement of the GP practice within the feasibility study. The involvement of the whole practice (including administrative and healthcare professional

team members) is important to enable the delivery of the feasibility study and to support the provision of joined-up care for individual patients.

This section outlines what taking part in the PROMPPT feasibility study as a practice involves.

Practice staff may be the first point of contact for the patients regarding taking part in the PROMPPT feasibility study. All documentation for the questionnaire study and the process evaluation signposts the patients to the research study team at Keele University. However, we anticipate that patients may contact the practice with questions regarding the research study. With this in mind:

- Administrative teams will be provided with some FAQs that may help to address some questions that the patients may ask.
- If a question is asked that the practice staff member is unsure of the answer, we will encourage them to pass on the research team's contact details to the patient.

During the PROMPPT pain management review process (first assessment and subsequent follow-ups), patients may consult with another member of the healthcare team. For this reason, we encourage all clinical practice staff:

- To be aware of the PROMPPT feasibility study
- To be familiar with the aims of PROMPPT
- To be consistent in the communication about the aims of PROMPPT with patients

To support this approach, the training manual will be made available for other staff members, including a study summary that easily explains the PROMPPT feasibility study and what taking part in the study as a practice will involve. Consultation records based either in EMIS or SystmOne will identify when a patient has attended a PROMPPT review (**see training manual section 3.3.1, *Finding and using study documents in EMIS and SystmOne*.** to find out more about using study documentation within consulting software).

1.5.4 Study documentation

We have developed three forms for completion as part of the PROMPPT pain management review, two case report forms (CRF) and one patient-facing form called the "pain review plan & self-care information".

- The first assessment CRF
- The pain review plan & self-care information
- The follow-up CRF

The purpose of completing the CRF is to provide a clinical and research record of the consultation. The document is easy to complete and takes you through each stage of the consultation step-by-step. As you would in a normal consultation, it is important that the documents are completed within or shortly after the consultation.

We then ask you to email a copy of the completed CRF for that PROMPPT pain management review. We would like you to email CRFs for all PROMPPT pain management

reviews that take place (or are scheduled to take place) up to 3-months from the first scheduled PROMPPT pain management review. Within this 3-month time-frame, please email all CRFs to our PROMPPT study email address on the day of the consultation. For PROMPPT consultations that happen beyond this point, please continue to use the CRF for the clinical record only.

The pain review plan & self-care information was developed to be a patient facing document and should be completed by you alongside the patient. We do not need you to email us a copy of this record.

Training manual section 3.3, *Pain review plan & self-care information* will outline how to find the three forms within your consultation and how to complete them.

1.5.5 Safety reporting

Patient safety is of paramount importance in clinical research and safety reporting is a critical part of the PROMPPT feasibility study. The PROMPPT pain management review is considered to be evidence-based best practice and has the endorsement and credibility of the clinical community. Given this, the potential harms of this feasibility study are considered to be minimal. However, we can only confirm this via the safety reporting and review process.

What is a serious adverse event?

An adverse event is any medical occurrence that may or may be related to, or a consequence of participation in a research study. A Serious Adverse Event (SAE) in the context of this study would be defined as an untoward occurrence that:

(a) results in death;

(b) is life-threatening;

(c) requires hospitalisation;

(d) results in persistent or significant disability or incapacity;

(e) is otherwise considered medically significant.

We know that reducing opioids can result a transient increase in pain and/or withdrawal symptoms but these events are not considered to be SAEs.

Reporting adverse events

It is important to report an SAE as soon as you, or the patient's GP become aware of them during the study. We need to hear about SAE's that occur at any point during the three phases of the feasibility study. In the event of an SAE occurring 3-months from the point that a patient is invited to attend a pain management review the research team must be notified:

- via telephone +44 (0)1782 732950 within 24 hours of becoming aware of the event AND
- via email sch-tr.studypromppt@nhs.net

If an SAE occurs 3-months after attending (or having been scheduled) a pain management review, the research team does not need to be notified.

Adverse events that are not SAEs do not need to be reported, however, it is important to record adverse events for your clinical record as well as for research purposes. You should record any adverse event on a CRF and email the research team on the same day as the appointment with a patient.

Module 2: PROMPPT Consultation Skills

2.1 Communication skills

(See also: E-learning course- PROMPPT Communication Skills, Communication Skills)

PROMPPT aims to support patients, where appropriate, to reduce their use of opioids for persistent pain. However, when healthcare professionals ask patients whether they wish to make changes to opioids, this often meets resistance. Simply lecturing patients on the potential harms of opioids is unlikely to be effective in overcoming this resistance or in achieving sustained opioid reduction. Patients' fear of pain getting worse often outweighs concerns about potential harms, which they may consider are not relevant to them personally (Frank, et al., 2016), such that attempts to provide information about opioids are met with defensiveness.

In order to support patients to make changes to their opioids, a more collaborative approach is needed. The PROMPPT review, therefore, draws on good communication skills and other principles of Motivational Interviewing to foster behaviour change. In this approach, reflective listening and questions to clarify and explore come before explaining or informing (Crawley, et al., 2018). These skills are outlined in the sections below and the linked training modules.

2.1.1 Active listening

It is recommended that the initial PROMPPT pain management review begins by you asking the patient to tell you about their pain and what they feel is most important for you to know. This provides an opportunity for patients to tell their pain story and your role is to listen. Clinicians interrupt patients on average after 12 seconds (Rhoades, et al., 2001) and these interruptions are not usually helpful (Li, et al., 2008). To create an environment amenable to guiding patients towards change talk, you need to fully hear and understand the patient through *active listening*.

True active listening only really occurs if the interviewer understands what the person is thinking, rather than just hearing the words. This is relatively easy if you have a confident, articulate patient who is open and explicitly expresses their thoughts. However, many people are anxious and inarticulate.

Some key skills for active listening:

- Allow the person time to gather her/his thoughts:
    - Appropriate use of silence
    - Supportive atmosphere
- Encourage the person to speak about the topic:
    - Displaying interest (eye contact, posture, not fidgeting)
    - Open questions
    - Verbal prompts (“yes, go on…”)
    - Non-verbal prompts (nodding)
    - Refrain from interrupting, especially the opening statement
    - Reflecting (repeating the last phrase)
- Concentrate on what the person says:
    - Avoid distractions (e.g. bleep, excessive note-taking)
    - Think about the person’s current answer, rather than formulating your next question
- Check understanding
    - Clarifying questions
    - Paraphrasing
    - Summarising

2.1.2 Demonstrating Empathy and Validation

The way healthcare providers respond to patients sharing their pain-related thoughts and feelings can impact significantly on patient satisfaction and engagement with pain consultations (Edmond & Keefe, 2015).

Many patients with chronic pain believe that others do not understand their pain or even consider their pain condition to be legitimate or real, particularly if the cause of pain is unclear, and this can increase psychological distress (Kool, et al., 2009).

Empathy and, in particular, the level of validation experienced by patients is increasingly felt to be an important component of effective communication during pain consultations.

Empathy is the ability to understand and share the feelings of another. In other words, being able to put oneself in another's shoes and feel what that person is going through and share their emotions and feelings.

Validation means acknowledging and accepting another person's internal experience as being valid without judgment. People who experience validation may report feeling their experience has been accepted/ acknowledged and feeling believed and/or taken seriously.

As the clinician conducting a pain consultation, validation means communicating to the patient that you understand their pain experience and accept it as real. Validation does not mean that you necessarily agree with all the patient's thoughts and feelings about their pain, rather that you accept them as valid and understandable. Instead of disputing or discounting their experience, validation provides opportunities to understand and normalise the patient's experience and may help to gently promote acceptance.

Table 2.1 Examples of validating and invalidating responses

Patient	Clinician	
	Validating response	Invalidating response
I am so worried because my pain is worse again today.	It's understandable that you're feeling anxious during a pain flare; a lot of people might feel that way in your shoes.	Is pain worse in the morning or the evening?
The pain is just awful and my GP keeps sending me to the physio but it's a waste of time.	It sounds like the things your GP has suggested really haven't helped and that sounds frustrating.	How long did you keep trying to do the exercises?
Pain keeps me up all day and all night, I'm never ever going to get better and now I've lost my job, I'm a burden to my family.	Listening to you, it seems to me that pain is affecting all areas of your life…that must be hard.	I'm sure your family doesn't feel that way. Where do you feel the pain at its worst?

What are the potential benefits of validation in pain consultations?

By acknowledging the patients' experience, validation can defuse emotional distress and this fosters listening and engagement in the consultation. Invalidation, on the other hand, often results in further attempts to convince and increases distress. If a patient keeps repeating

the story of their suffering, especially if it is embellished with each telling, then they probably do NOT feel validated and it is useful to watch out for this during consultations.

Empathic, validating communication helps build trust, making it more likely that patients disclose relevant information, thus promoting problem solving and shared decision making (Linton, 2015).

Experimental studies exploring the impact of validation in the context of pain have reported benefits in terms of mood and satisfaction with interactions when participants received validation compared with invalidation (Edmond & Keefe, 2015).

Validation has also been shown to improve recall during an experimental pain test (Carstens, et al., 2017), which is important because pain and pain-related distress may result in poor recall of advice and instructions given in pain consultations and strategies to enhance recall have the potential to improve adherence to treatment plans.

Training medical students in empathetic validation increased validating responses and reduced invalidating responses leading to improved communication with simulated 'pain patients' and greater 'patient' and medical student satisfaction with the interaction (Linton, et al., 2017).

2.2 Using the Pain Concerns form to explore persistent pain more widely

(See also: E-learning course- PROMPPT Communication Skills, Using the PROMPPT Pain Concerns Form to explore persistent pain more widely)

In the Foundation Course we outlined that persistent pain impacts on the wider aspects of an individual patient's life. We also introduced you to the Pain Concerns form which aims to facilitate conversations during pain review consultations. This lesson outlines how you can use the PROMPPT Pain Concerns Form to allow patients to raise concerns about the wider issues of living with pain that they might not always feel is relevant to raise in a consultation about their opioid medicines. The responses to statements in the Pain Concern Form may provide a useful starting point for a conversation exploring their persistent pain experience in more detail.

The majority of PROMPPT consultations will take place remotely rather than face to face. The best approach to using the form in remote consultations will be to ask the patient whether they have their copy of the form in front of them and check whether they have had an opportunity to read and complete the form as requested in the invitation letter. Then our suggestion is to go through the form verbally, section by section, making a note of patient responses in order that you start to build up an understanding of how pain is having an impact on the wider aspects of their life.

Earlier sections have highlighted the importance of reflective listening, empathy and validation **(training manual section 2.1, *Communication skills*)** to help the patient feel heard and understood. Understanding some of the possible concerns that patients may have and that may lead them to agree with statements on the Pain Concerns Form is useful to

consider (see table 2.2) . The next step would be to ask open questions and then to validate their experiences consistent to the approach outlined in previous sections.

Table 2.2 Examples of Pain Concerns that may lead to agreement with statements on the PROMPPT Pain Concerns Form

PROMPPT Pain Concerns Form section header	Examples of patient concerns
About my pain	• What is causing my pain? • Is there anything more that can be done to find out what is wrong? • Should I have more investigations? • Is there anything more that can be done [*to reduce/ control/help*] my pain?
Because of my pain	• How can I do the things I want to be doing when I've got pain? • What can I do to get a good night's sleep? • What can I do to stop me feeling [*stressed/low*]? • How can I explain to people about the effect my pain has on me?
Regarding the medicines I take for pain…	• Will I become addicted to the medicines I take? • Are there other ways to treat my pain that does not take medicines? • Will these medicines harm me? • I don't want you to stop my medicines

Once you have an understanding of how pain impacts on the wider aspects of their life you can then ask open questions and questions to get permission, as follows:

- to get a deeper understanding of the problem
    - Ask "can you tell me a bit more about [*that*]?",
- to prioritise concerns
    - Ask "of the statements you have agreed with, can you tell me about those that are of most concern?"
- and guide the consultation
    - Ask "how would you feel about some information on this?"
    - Ask "what thoughts have you had about how I can help you?"
    - Getting permission "Can we leave this for now and then come back to it at another point?"
    - Getting permission "Can I get back to you about this after I have spoken to [*your GP*/ my colleague"]

The next section in this handbook builds on the early conversations with patients using the Pain Concerns form and outlines how to guide the conversation about the effects of opioid medicines. We'll revisit some of the concerns that patients have in later sections of this manual, **training manual section 2.6, *Talking about opioids*** will outline how to talk about persistent pain with those patients with specific concerns and we outline how to support patients to do the things they want to be doing in **training manual module 3, *PROMPPT Pain Management Skills*.**

2.3 Exploring the effects of opioids

(See also: E-learning course- PROMPPT Communication Skills, Exploring the effects of opioids)

As discussed already, patients often have strong opinions about their opioids, and discussions about opioids can often encounter defensiveness. Active listening with reflection of an individual patient's own experiences and concerns back to them can help defuse some of this defensiveness. The aim here is to gently explore the effects of opioids (wanted and unwanted) experienced by the patient so that their own experience, rather than their assumptions about opioids, can provide reasons for change, if this is appropriate for them.

Best practice guidelines recommend considering the 4A's (see box below) when exploring the benefits and downsides of opioids.

The 4 A's

Analgesia (pain relief)

Activity (functional improvement)

Adverse effects (side-effects, complications)

Aberrant behaviour (evidence of non-compliance with prescribed regimen/ opioid misuse e.g. requesting prescriptions early and / or from multiple prescribers)

In the initial PROMPPT consultation, information obtained from listening to the patient's story **(training manual section 2.1, *Communication skills*)** and/or from their Pain Concerns Form **(training manual section 2.2, *Using the Pain Concerns form to explore persistent pain more widely*)** and from the electronic medical record can offer a natural starting points for personalised discussion about the effects of opioids, encompassing these four areas.

Listening

As the patient tells their story, listen out for anything that gives a sense of their perspective on opioids and might indicate a desire, reason or need to make a change. For example:

- Statements indicating that the opioids don't help or don't work like they used to
- Symptoms that may be opioid-related side-effects e.g. constipation, poor concentration / memory, tiredness, nausea, itching

- Functional impact of pain – even with opioids
- Concerns about taking pain medicines/opioids long-term and potential harms of long-term opioid use
- Concerns about opioids being stopped
- Desire for dose increase
- Running out early

You can then start the conversation about opioids by reflecting back what the patient has told you, for example:

Patient (when telling their story): This back pain is really getting me down. I wake up, and I feel so stiff. Most days I can hardly get out of bed. It doesn't really get much better during the day so I can't do any of the things I need to do, like housework and cooking – I can't even play with my kids.

Clinician (starting to explore the effects of opioids): From what you've told me, it sounds like you are really struggling with the pain and pain is still stopping you from doing the things you want to do.

Patient: Exactly! I want to get back to doing all the things I used to but it's impossible with this much pain.

Clinician: You want to get back to a normal life, but even though you take Tramadol, this isn't helping you do that at the moment.

Patient: No…….it used to at first, not sure what happened

Reflecting on the Pain Concerns Form

Another way into a conversation about opioids is to reflect the patient's responses about medicines on the Pain Concerns form back to them. This can be a useful way to explore whether there are functional benefits from opioids. For example:

The patient takes morphine and has ticked that they agree with the following statements on the Pain Concerns Form:

- My pain is getting worse
- Because of my pain:
    - "I can't do my usual day-to-day activities"
    - "I can't continue or return to work
- "I am concerned that these medicines do not help my pain enough"

Clinician: Looking at your form it seems like pain is stopping you doing all the things you want to do, even with the medicines and you're concerned that morphine doesn't help enough, in fact your pain is getting worse?

Patient: Yeah, I think I need a stronger dose.

Clinician: You're wondering if a higher dose might work better.

Patient: I know it will. In the past when my doctor increased the dose I always felt better.

Clinician: And when you felt better, maybe you could do your housework and cooking again

Patient: Well no, not really, but I did feel like I could forget about the pain for a while.

Asking questions

Questions should be used to explore the patient's experience and perspective on opioids by clarifying and expanding on what they have already told you and exploring other aspects as needed.

Aim to listen to their responses without judgment, disapproval or advice, even if the patient expresses inaccurate / mistaken beliefs about opioids and/ or seems resistant to making changes. Patients often have strong opinions about opioids and jumping in too soon to 'correct' the patient's perspective can make them increasingly defensive, more likely to 'dig their heels in' and more resistant to change. Instead, try to defuse defensiveness with active listening. Taking time to reflect the patient's responses back to them before moving on to the next questions helps clarify your understanding, may yield further useful information and prevents the patient being bombarded with questions.

Closed questions such as 'Does the morphine help you?' often elicit uninformative responses along the lines of 'It takes the edge off', or "I'm sure I'd be worse without it".

Where possible opt for open questions that encourage the patient to reflect on their actual experience of taking opioids for persistent pain rather than any assumptions they may have about the effects of opioids.

Some patients may prefer or need specific prompts about common side-effects as shown in the box below.

Opioid Side-effects

- Constipation, nausea, feeling dizzy/unsteady, dry mouth, weight gain, sweating, loss of libido/impotence, itching
- Confusion, difficulty concentrating, drowsiness, memory problems, mood changes

For example, for a patient taking regular morphine:

Analgesia	“From your point of view, what are the benefits you notice from continuing to take morphine?”
Activity	“How has what you do (can do?) day-to-day changed since you have been taking morphine?”
Adverse effects	“What are the downsides, for you, of continuing to take morphine?” “What unwanted effects (effects that you do not like) do you notice from taking morphine?” (consider asking specifically about common side-effects) “ Suppose you carry on taking opioids for the next 5 or 10 years, what do you think that would be like?”
Aberrant behaviour	“How do you usually take your morphine? (compare this to prescription) “What concerns do you have about taking morphine?” Or if a potential problem is apparent from the medical record e.g. patient requesting prescriptions early, ask specific questions about that to find out more.

During the consultation, you may find it helpful to jot down the patient’s perceived upsides and downsides of continuing and reducing/stopping opioids in a way that helps you reflect a summary of these back to the patient. You can simply list these to aid a verbal summary or create a table or diagram depending on what you find most helpful and practical to incorporate into your consultation.

In addition to asking questions relating to the ‘4A’s’, it is also useful to ask about what potential advantages the patient may envisage if they reduced or stopped opioids, and what concerns they have about doing this. Concerns about pain getting worse and/or withdrawal symptoms are common and previous experience of stopping abruptly or missing doses may be fuelling these concerns. A very useful question to ask all patients therefore is “Have you ever run out of your [name of opioid] or suddenly stopped taking it for any reason?” and, if so, ask what happened, what did they notice and how did they feel. If patients experienced worse pain and/or withdrawal symptoms they may not only fear reducing again but may also harbour concerns that they are addicted and may benefit from some information about this

When trying to build a complete picture of patients’ experience and concerns, remember that asking ‘is there something else?’ or ‘what else?’ is more likely to generate additional responses than asking ‘is there anything else?’ (Heritage, et al., 2007).

Explaining /Informing

Providing information may be useful in supporting an informed discussion about the effects of opioids. However, this needs to come at the right time, after listening and asking questions, ideally with the patient's permission and certainly not in the form of a lecture! For example, if the patient has told you their opioid no longer works so well and they think a higher dose is needed, you may ask if you can share some information about why this might be and then explain about opioid tolerance. Then you can seek feedback on what they think of this and, if needed seek permission to share some more. Explaining the problems associated with opioids is covered in more detail in **training manual section 2.6, *Talking about opioids*.**

2.4 Fostering behaviour change

(See also: E-learning course- PROMPPT Communication Skills, Fostering behaviour change)

So far, we have looked at the communication skills that help engage patients in discussion about change in order to build an understanding of the patient's perspective on opioids and what might motivate them to change **(training manual sections 2.1, *Communication Skills*, 2.2, *Using the Pain Concerns form to explore persistent pain more widely* & 2.3, *Exploring the effects of opioids*).** Patient's attitudes and readiness to change will vary and whilst some patients may be interested and ready to take the next steps, as they dislike the medication and/or feel it is ineffective, many will have mixed and contradictory feelings and some may not be interested at all. This may be because they are satisfied that their medicines are helping them or they may be resistant because they fear increased pain and/or withdrawal effects.

Motivational interviewing aims to help patients explore their own reasons for and against change rather than the healthcare professional taking on the role of expert informing patients why and how they should change.

2.4.1 Exploring ambivalence

Ambivalence is a natural response to change and anyone making a change might have reasons why they might (enablers) and might not (barriers). When it comes to reducing opioids, a common statement might be, "I have some worries about taking these medicines and I know they can be addictive, but I don't think I can cope without them". Table 2.3 provides a summary of some of the reasons that patients might want to make changes and table 2.4 looks at some of the reasons they might not.

Table 2.3. Patient enablers to reducing regular opioid medicines. Adapted from (O'Connor, et al., 2019)

Patient enablers to reducing opioids	
Actual or perceived adverse effects of opioids	Side effects and/or of addiction Pharmacist (or other HCP expressing safety concerns) Patient willing to make some changes to reduce side effects
Social support for patients	Peer experiences and advice Family and friends support during taper and helping to recognise side-effects

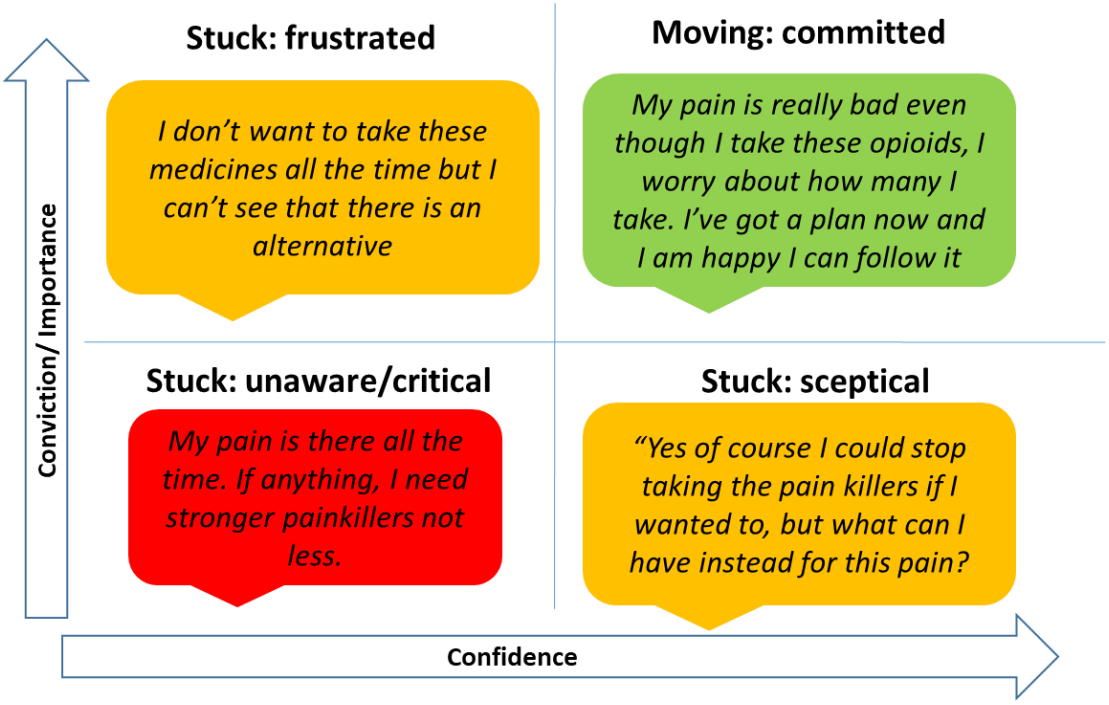
Table 2.4 Patient barriers to reducing regular opioid medicines. Adapted from (O'Connor, et al., 2019)

Patient barriers to reducing opioids	
Limited alternatives to opioids	Pharmacological Patient finds it difficult to engage with self-care
Patient priority to reduce/ control pain, not opioid side effects	Current pain trumps future risk Opioids needed to function and for current quality of life
Reluctance to change therapy if stable	Patient has concerns about reducing/ stopping fear of cessation, withdrawal, or pain returning
Patient understanding and expectations	Patients expect long-term treatment Patients have low perceived risk of adverse effects Patients feel that opioid reduction means that the pharmacist doesn't care about their pain/health
Pressure from health care professionals	Pressure and/or mixed messages to reduce/ stop from pharmacist and/or other health care professionals may threaten the relationship

2.4.2 Assessing readiness to change

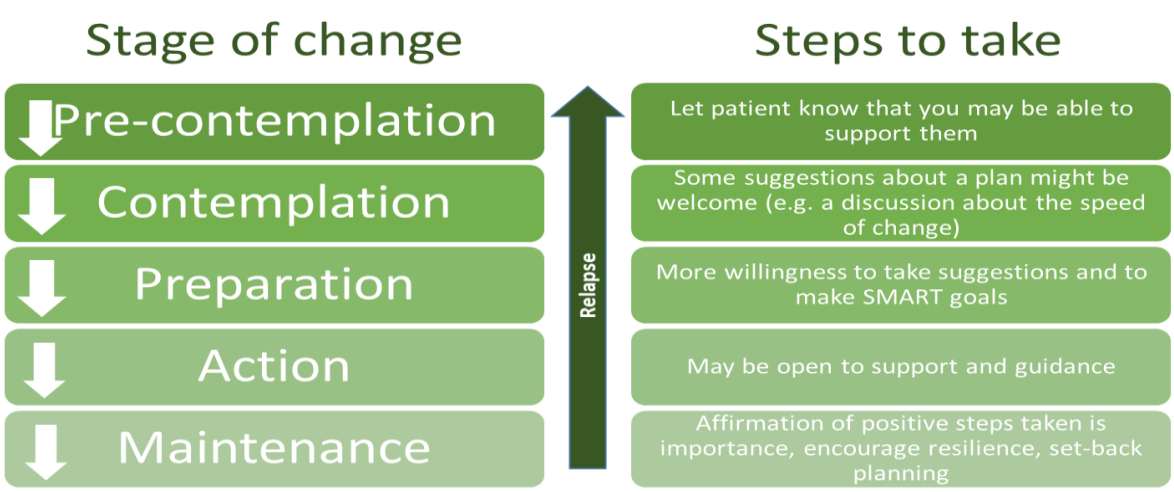
Ambivalence creates an internal conflict about making a change and often leads to indecision that is less likely to result in a commitment to make change. Ambivalence often doesn't go away and can be present if the patient has a set-back. For patients to move forwards, the desire to make a change needs to be greater than the barriers that presents. One of the ways of exploring ambivalence and readiness to change is to have an understanding of the patient's confidence to make a change and the conviction (importance) that this change holds for them (see figure 2.1). In the red speech bubble, the patient seems unaware of the need to make any change. Both confidence and importance seem low, the patient is quick to defend their position and it is likely that this patient has not contemplated any change. Whereas, patients who see making changes with more importance and more confidence may be ready to take action.

Figure 2.1. Readiness to change: exploring importance vs confidence to reduce/stop opioids



Another way to think of readiness to change is in 5 stages, pre-contemplation, contemplation, preparation, action and maintenance and the goal is to move through the stages to maintenance, see figure 2.2. As a patient moves through stages of change, their confidence improves and importance grows, although not always at the same time. The best steps for the pharmacist to take to support the patient will vary depending on the stage of change they are at. A relapse, or a set-back **(training manual section 3.2.4, *Set-back planning*)**, can happen at any stage and is characterised by them going back to their original prescribed dose. A relapse is different to a lapse which is more momentary and may involve for example, an occasional increase in the number of PRN opioids they take in response to an increase in pain.

Figure 2.2 Readiness to change in stages



This article **(also accessed from training manual section 4.6, *Additional learning materials*)** provides a more detailed account of how motivational interviewing can be used in conversations about opioid tapering with patients who have persistent pain.

2.5 Talking about persistent pain

(See also: E-learning course- PROMPPT Communication Skills, Talking about persistent pain)

During the course of the PROMPPT consultation, a patient may express thoughts that something related to their pain has been missed, and they may indicate this on the Pain Concerns form. It is useful for patients to understand that in varying degrees, their pain and symptoms are likely to be caused by pain sensitisation.

Many patients will have been given an explanation for their pain at some point, and may have been happy with this explanation. For patients with questions about their pain, using metaphors can be a useful way to describe the process of pain sensitisation. One useful metaphor is to think about pain as an alarm system:

> *Pain is like a house or car alarm. Normally that alarm only goes off when there is an intruder, or someone breaks a window. But when pain goes on for a long-time, like yours, we know that the alarm system re-sets itself so that when the wind blows it triggers an alarm. We call that pain sensitisation.*

This explanation is often sufficient for many patients, but a few may remain stuck and sometimes this is when they have to be given an alternative explanation that is more tangible. In these cases, for example, a patient with sciatica, we then explain that it is less

about what caused the pain in the first place (and patients will often refer to a slipped disc) and more about why the pain is not getting better.

If the patient remains stuck, a suggestion would be to step back and find common ground in order to validate their experience. This common ground might be an agreement between you and the patient that whatever the cause of the pain, there does not seem to be a quick fix for their pain or that medicines don't seem to be the answer. With common ground established, the next step would be to help the patients to shift their focus away from their pain, whatever its explanation and move their focus towards taking steps to self-care **(training manual section 2.8, *Shifting the conversation to self-care*).**

Talking about pain can be difficult, we have developed a leaflet and there is a useful video to support you and the patient **(also accessed from training manual section 4.5, *Patient information resources*)** There may be times when this continues to be a barrier to making progress (for example, it is inconsistent with other explanations, or when the patient is actively seeking further investigations). An option would be to liaise with the GP if you need further support to help the patient move forwards with their pain.

2.6 Talking about opioids

(See also: E-learning course- PROMPPT Communication Skills, Talking about opioids)

Having explored the effects of opioids, you should have an understanding of how well opioids are working for your patient, whether reducing opioids seems appropriate and how ready the patient is to contemplate this change. Along the way you may have identified some mistaken beliefs about opioids, concerns about reducing them or at least some gaps in the patient's knowledge. As already mentioned, attempting to address these with a generic 'lecture' on opioids and the potential harms is unlikely to be helpful. On the other hand, providing information that is personalised and relevant to patients' misunderstandings and concerns, in a non-judgmental way, can support them to make an informed decision about reducing opioids.

Bear in mind that patients will only remember a small proportion of what is said in a consultation, so you need to keeping explanations brief, focusing on the key issues they have raised and supplement this by signposting to relevant information resources, which they can explore at their own pace following the consultation **(see training manual section 3.3, *Patient review plan and self-care information*,** for information on how to create a review plan and **section 4.3, *Pain review plan & self-care information*** for a copy of the review plan).

Below are some simple explanations relevant to commonly held beliefs and concerns:

Explaining why opioids often don't work for persistent pain

This is particularly relevant to patients who:

- believe opioids 'must work' because they are 'strong painkillers'
- believe their pain would be even worse without opioids
- feel that there must be a drug that will get rid of this pain, etc.

Opioids are strong painkillers and they work pretty well for short term pain and cancer pain at the end of life. Long-term (persistent, chronic) pain is different – it's very complex and influenced by lots of different factors. Any medicine can only act on one part of this very complex system and if that isn't what's causing the pain, the medicine won't help. Some pains don't seem to respond to any medicines.

Explaining about tolerance / why opioids stop working

This is particularly relevant to patients who:

- feel opioids helped at first, but aren't helping so much now
- believe they need a higher dose / stronger opioid

When people take opioids regularly, it's very common to notice less and less benefit as time goes on. This is because your body gets used to the opioids and stops responding to them. This is called building up tolerance. Increasing the dose isn't the answer, even if it seems to help at first, you will soon become tolerant to the higher dose and it's likely to cause more side-effects and other problems.

Explaining the potential long-term harms of opioids

This is relevant to all patients taking regular opioids and should be tailored to their experience of any benefits / side-effects and their personal risk factors. For example:

You can discuss how any unwanted side-effects of opioids (include personal examples) may interfere with their ability to engage in activities that would improve their quality of life and wellbeing. For example, daytime sleepiness stopping them going out, or being able to concentrate to read a book they might otherwise enjoy.

You can explain that research studies (or scientists) have discovered that people taking long-term opioids are more likely to develop other problems and then highlight those of particular relevance from the following: more likely to fall, have lower sex drive, be more prone to infections, and have poorer quality sleep, low mood, reduced fertility.

You can also explain that as well as developing tolerance, people who regularly take opioids can develop increased pain sensitivity, meaning their opioids actually make the pain worse and they may start to hurt all over *(opioid-induced hyperalgesia)*.

Explaining why pain isn't necessarily worse if opioids are reduced

This is particularly relevant to patients who:

- believe opioids 'must work'
- fear their pain will be even worse if opioids are reduced.

It's understandable to be concerned that pain will be even worse if opioids are reduced or stopped but our experience is that most people do not suffer worse pain if opioids are tapered gradually with the support of a healthcare professional. Some people may notice a short term increase in pain, but this usually settles within a few weeks, and many people say they feel better overall, probably because they have fewer side-effects of opioids.

Explaining about physical dependence and withdrawal symptoms

This is particularly relevant to patients who:

- have experienced worse pain after stopping opioids abruptly / missing doses / reducing rapidly
- believe that opioids are helping because pain was worse after stopping/ reducing opioids abruptly in the past
- are concerned about the possibility of withdrawal symptoms if they reduce
- are concerned that they experience symptoms of withdrawal prior to the next dose being used and/ or are concerned that this may mean they are addicted to opioids

It is common for people who take opioids regularly to become physically dependent on them. This means that if you run out or stop taking opioids suddenly, you can get withdrawal symptoms such as worse pain, feeling restless, feeling anxious or irritable, sweating, aching muscles, diarrhoea, stomach cramps and a runny nose. But physical dependence is not the same as addiction and it is possible to come off opioids without withdrawal symptoms by gradually reducing the dose, a little at a time, to give your body chance to adjust.

or

Most people who are prescribed opioid medicines for long-term pain do not become addicted to opioids, but around 1 in 10 people may develop signs of addiction such as craving their opioid medicine, feeling out of control about how much they take or how often, and continuing to take it even when it has a negative effect on their physical or mental health.

Explaining why we are concerned about opioids now / what has changed

This is particularly relevant to patients who:

- expressed frustration at being started on opioids in the first place
- have questioned why their GP has continued to prescribe opioids if opioids don't work for long-term pain/are harmful
- have questioned the need to reduce as the GP has always prescribed them before

It's understandable that you are confused (or frustrated or angry). You've been prescribed opioids for all this time, through no fault of your own, and now we're suggesting this may not be such a good idea. What's changed is that research studies have helped us better understand the longer-term effects and risks of opioids and that changes the advice we give about opioids - because your safety is our top priority.

Take some time to look through the patient resources (all accessed from **training manual section 4.5, *Patient information resources***) so that you are familiar with them, this will help you in knowing which resources to signpost a patient to. Of particular relevance to this section are: The problems with opioids and persistent pain, Brainman stops his opioids, What to expect when you reduce opioids and what might help, Louise's story, Lisa's story and Sean's story.

2.7 Talking about mental health problems

(See also: E-learning course- PROMPPT Communication Skills, Talking about mental health problems)

It can be difficult to live with pain and it is not uncommon for patients consulting with pain to be low in mood or to have some anxiety. It is likely that some patients will have mental health problems unrelated to their pain. Some of this information may be gathered from their responses to the Pain Concerns Form. Some patients with mental health problems both related and unrelated to pain will have a good awareness of their condition with helpful strategies and robust support, but this may not be the case for all patients.

We suggest you approach mental health problems in the same way we have outlined for assessing pain. You could start by validating their experience and ask open questions to get a better understanding. For example:

Validate: “You’ve told me [*that the pain gets you down/ that you’ve struggled with anxiety before*] and that must make it harder to cope with the pain.”

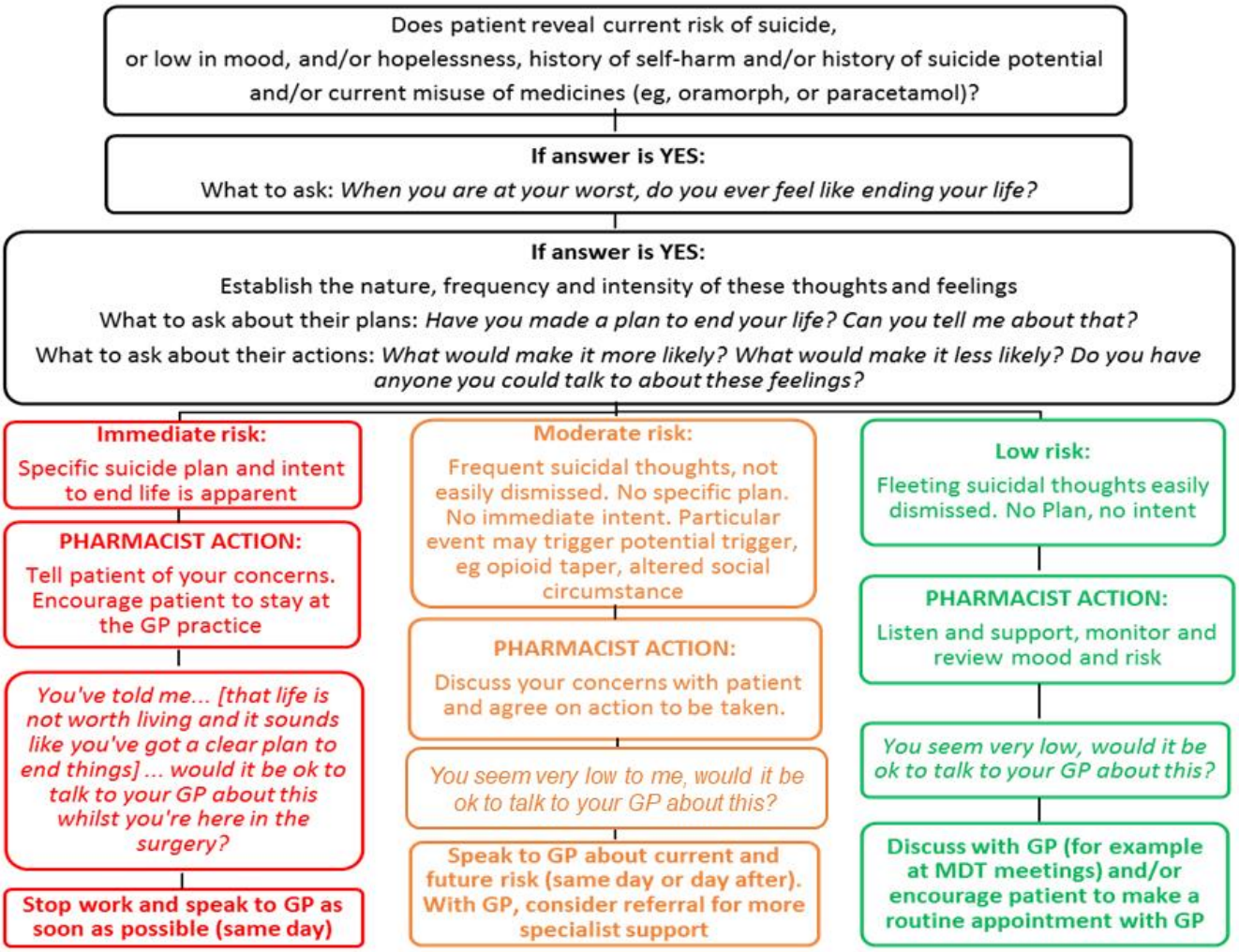
Ask: “How would you feel about [getting more support/ learning different ways to manage] your mood?”

2.7.1 Assessing risk in patients who are low in mood

During a consultation, a patient may reveal suicidal thoughts, or may be particularly low, depressed and/or withdrawn during a consultation. If a patient reveals suicidal thoughts, or is particularly low, depressed and/or withdrawn during a consultation, let them know that you are listening to them and ask them more about the thoughts they are having. Take them seriously and in discussion with the patient make a plan to discuss the case with the GP.

Figure 2.3 outlines what to ask patients if they reveal a current risk of suicide and what action to take, if needed.

Figure 2.3 Assessing current risk of suicide in patients consulting with a pharmacist in primary care.



In **training manual section 3.4** we will outline when it would be important to collaborate with the GP about a patient's mental health and the next steps you could take when the patient is not at immediate risk.

2.8 Shifting the conversation to self-care
(See also: E-learning course- PROMPPT Communication Skills, Shifting the conversation to self-care)

A natural and often first response for patients when talking about the possibility of reducing their regular opioid use is to ask "what else?" there is for their pain. In the PROMPPT Foundation Course we introduced the concept of the pain cycle and the route out of this cycle through self-care **(training manual section 1.2.1, *Persistent pain and the role of self-management*)**.

We know that it can feel difficult to shift the conversation away from pain control to focus instead on the self-care. This section explains how you can support the patient to move away from a passive approach (taking pain medicines/ having treatment done to them) towards an active approach whereby they learn to live well with pain using self-care strategies.

Many patients who attend a PROMPPT review will use some self-care strategies alongside using their pain medicines and it is worth exploring this in a consultation, for example:

Ask: Other than your pain medicines, what things do you do to help you get by with your pain?

A question like this may help the patient to talk about the strategies that they actively engage with to help them get on with life with their pain. In some consultations, the patients will find this type of question difficult to respond to. This is often the case in consultations where there is a lot of pain-talk and where the patient is more oriented to reducing pain. Often in these circumstances the patient may find it difficult to identify those strategies that are to some extent helpful.

In these consultations a useful question that may elicit a shift away from pain could be to ask:

Ask: Why do you want to have less pain?

Or

Ask: What would you be doing if you have less pain?

In all but the most stuck patients this follow-up question often elicits a values-based response and a shift away from pain-talk.

2.9 Agreeing a management plan

(See also: E-learning course- PROMPPT Communication Skills, Agreeing a management plan)

2.9.1 Shared decision making

When considering developing an agreed management plan for patients with chronic pain, it is important to consider the concept of shared decision making. This is defined as:

‘an approach where clinicians and patients share the best available evidence when faced with the task of making decisions, and where patients are supported to consider options, to achieve informed preferences’

Although it is not a new concept, some clinicians find the process of negotiating an agreed management plan difficult. In 2018, 17% of patients stated that they did not feel they were involved in decisions about their care – a figure that has remained unchanged in 10 years.

As the medical expert, clinicians can find it challenging to translate the medical knowledge and management options, into a form understandable to patients and their own values, desires, preferences, and concerns. It is important to consider the roles of the patient and clinician and these are in table 2.5.

Table 2.5 The roles of the patient and clinician in shared decision making

Clinician's expertise	Patient's expertise
Diagnosis	Experience of illness
Disease aetiology	Social circumstances
Prognosis	Attitude to risk
Treatment options	Values
Outcome probabilities	Preferences

Principles of shared decision making

- Respect
    - Self determination
    - Relational autonomy
- Information gathering (what matters most)
- Information giving
- Managing options/choice
- Explore preferences
- Developing a mutually agreeable plan

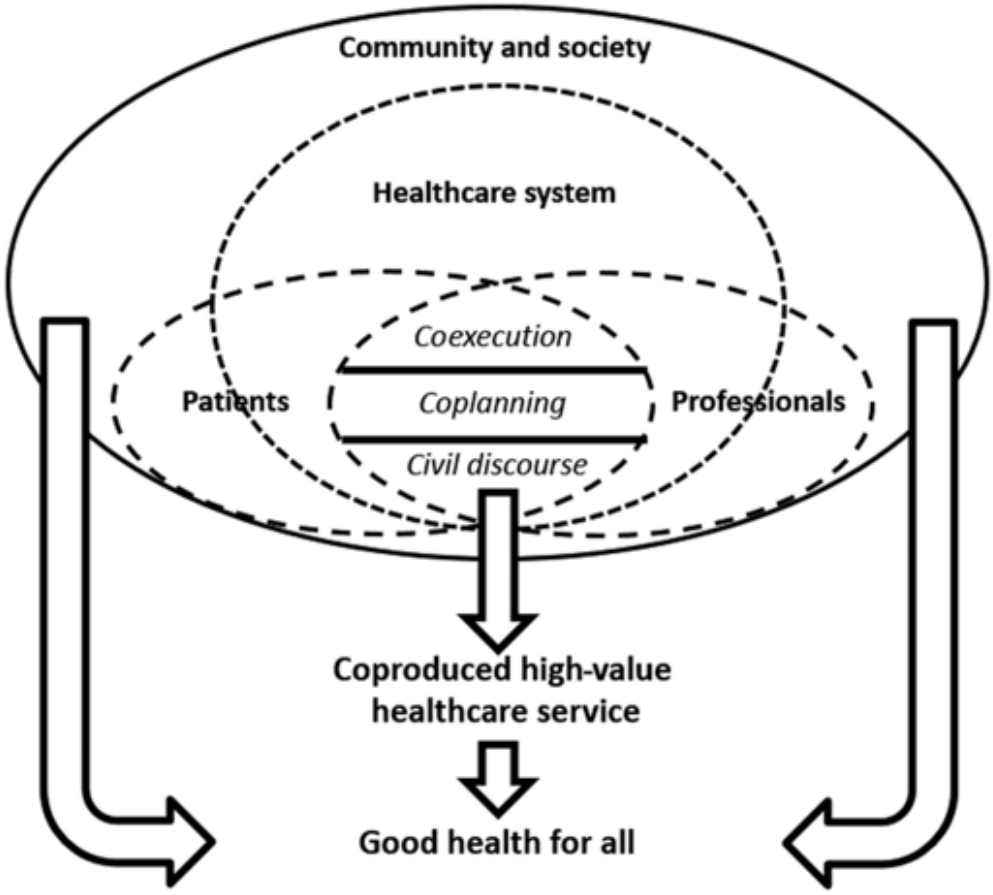
Why is shared decision making important?

- Improved patient knowledge of their condition and treatment options
- Increased patient confidence to self-manage aspects of their own care

- Increased likelihood of adherence to chosen course of treatment and participation in monitoring
- Improved satisfaction with care and chosen treatment
- More accurate risk perceptions by patients
- Reduced length of hospital stays and readmission rates

So decision-making and negotiating management options with patients is clearly a collaborative process and the coproduction model (Batalden, et al., 2016) builds on this concept (see figure 2.4). It highlights the factors involved in the decision-making process and shows how healthcare is something we do with our patients, rather than to them.

Figure 2.4 Coproduction model (Batalden, et al., 2016)



Managing conflict

Having built on your experiences of communicating with patients with persistent pain, validating their experiences and concerns, exploring their motivation for change and shared the decision-making process, it is hoped that the consultation goes well. Sometimes though,

there are areas of conflict within the consultation and it is worth exploring this in more detail to look at ways of avoiding and managing it.

The ‘heartsink’ patient

“Patients in every practice who give the clinician and practice staff a feeling of ‘heartsink’ every time they consult. They evoke an overwhelming feeling of exasperation, defeat and sometimes plain dislike that causes the heart to sink when they consult.” (O'Dowd, 1988).

Working in clinical practice, we may all have come across a small number of patients who make the heart sink when they consult. A number of factors may contribute to ‘heartsink’ patients, and it is important to recognise that there are as many clinician contributing factors as there are patient factors (see figure 2.6).

Figure 2.6 Patient and clinician factors contributing to a ‘heartsink’ patient

Clinician Factors	Patient Factors
Fear	Fear
Stress/Anxiety	Mental health problems
Uncertainty/Lack of experience	Personality disorders
Low morale	Previous poor care
Poor communication skills	Concomitant serious illness
Over patient-centred	Frequent flyer

What can you do to manage this?

Some of the skills required to reduce the risk of having a challenging consultation have already been discussed in the manual and you may already be employing these in your day to day practice. These include:

- Improved listening and understanding
- Improved partnerships with patients
- Improved skills at expressing negative emotion

- Ensuring understanding of patients' emotional responses to conditions and care
- Negotiating the process of care
- Sharing uncertainty

2.9.2 UNITED negotiating process

Outlined below is the UNITED negotiating process, which is a structured approach to making a shared decision with a patient.

Understanding

1. Aim to obtain a detailed understanding of what the other person thinks and feels about the problem.
    - Allow the other person time to express their view; use open questions
    - Use active listening skills (body language, reflecting, summarising etc.)
    - Identify and respond to verbal and non-verbal cues
    - Accept that the other person has a right to their views, even if their beliefs and attitudes may seem odd to you
    - Imagine how you might feel in their situation
    - Avoid making assumptions about their views – always check
    - Show you understand others' feelings and thoughts by showing empathy
2. Help the other person to **understand** your perspective on the problem
    - Set out clearly if you have an agenda or a position, and explain why
    - Give information in steps (Chunk and Check understanding)
3. Recognise that other unrelated issues may interfere with both parties' feelings and thoughts

Non–negotiable issues

Certain points may be so important to the other person that they will not under any circumstances wish to concede ground. Identify and clarify these in as much detail as possible. If you are not specific enough, negotiation becomes difficult. Demonstrate to the other person that you recognise the importance of the issue by paraphrasing or summarising.

Identify common ground

Conversely, there will be some issues on which you both agree. It is important to explicitly identify, clarify and acknowledge these.

Tensions remaining

Identify, clarify and acknowledge any specific differences or sticking points that remain between you.

Explore possible solutions

- Bearing in mind the above, tentatively float possible solutions and explore the advantages and disadvantages of each. “I wonder if we could…” is better than “You should…” or “Why don’t you…”
- Encourage the other person to come up with options as well. Consider asking them first for their ideas about the solution before suggesting other options.
- It may be helpful to follow through the hypothetical consequences of possible solutions suggested to explore their suitability and risks
- Chunk and check again when giving information

Decide together

- Agree to move forward on one of the above options.

There are links to a number of articles in **training manual section 4.6, *Additional learning materials***, which would make useful reading to further increase your knowledge of shared decision making.

Module 3: PROMPPT Pain Management Skills

3.1 Medicines Management

(See also: E-learning course- PROMPPT Pain Management Skills, Medicines management)

3.1.1 Opioid tapering

So far we have looked at how PROMPPT consultations can help patients identify their own reasons for and against continuing opioids, and how you can support them to consider reducing opioids, where this is appropriate. This section offers a step-by-step guide to managing the opioid reduction, where this has been agreed with the patient.

Preparing the patient for tapering

- Make sure the patient knows that opioids should be tapered gradually and not stopped suddenly and that the reduction will take time, often months not weeks, especially if they are on high doses
- Explain what to expect including:
    - Whilst it is unlikely that pain will increase longer-term, some patients experience tiredness, restlessness, and/or an increase in their usual pain following opioid dose reduction
    - Only a few people report withdrawal symptoms (see box below) following gradual tapering, although patients may fear this if they have stopped or reduced opioids abruptly in the past

Withdrawal Symptoms

Patients experience withdrawals differently and may experience none, some or all of the symptoms below:

- Sweating, yawning, tremor, abdominal cramps, diarrhoea, restlessness, irritability, anxiety & runny nose/eyes
- Bone or joint aches, which may be confused with perceived worsening of the original pain

- Reassure that withdrawal symptoms are temporary and any increase in their usual pain is unlikely to persist long-term. Most people do not experience worse pain following opioid reduction and many notice an overall improvement because they are having fewer side effects

- Encourage the patient to reflect on their previous experience of pain symptoms fluctuating, with 'good and 'bad' days even when opioids remained stable or were increasing and explain that this variation is likely to continue

- Discuss self-management (self-care) strategies **(see training manual section 3.2, *Supporting self-care strategies*)**

- Signpost to relevant information resources about opioid tapering **(see training manual section 2.6, *Talking about opioids* and 4.5, *Patient information resources*)**

- Reassure them about how you will monitor and support them during the taper. Including arrangements for follow-up appointments and 'as required' contact between appointments **(see training manual section 3.5, *Next steps*)**

Creating a tapering schedule with the patient

- Agree whether the goal is stopping or tapering to lowest effective dose (with the option to consider further reduction then)

- Calculate total oral morphine equivalence of all current opioids by any route

    - Check with the patient what they are actually taking, don't assume the prescribed dose is being taken

    - Use the opioid equianalgesic calculator developed by the Faculty of Pain Medicine, Australian and New Zealand College of Anaesthetists (FPM ANZCA), to calculate the total morphine equivalent daily dose (MED). The calculator is available here and can also be downloaded as a smart phone application from the Apple App Store or Google Play Store

- Avoid switching to a different opioid in order to taper, instead reduce the dose of their currently prescribed opioid(s)

- Aim to taper the dose by around 10% of the original dose two weekly or monthly

    - The exact % reduction will depend on the dose units available

    - If the patient is particularly anxious, starting with a smaller dose decrease (e.g. 5% or even less) and reducing monthly, may help build confidence

    - Avoid reducing more frequently than every 2 weeks

    - When considering frequency of reductions, consider your capacity for follow up and review, taking into account any periods of leave

- Remember that the dose reduction becomes a larger proportion of the dose as the dose reduces. Consider smaller dose reductions as the dose becomes lower, if the patient starts to run into difficulty

- If a patient is taking more than one opioid, reduce one at a time. Ideally start with the most potent

- If a patient is taking oral modified release (MR) opioids (including patches) as well as immediate release (IR), taper the MR / patch first. If they are taking IR liquid, switch to tablets to more easily monitor the amount used

- Limit number of doses of IR per day and counsel patient not to increase dose of IR to compensate

- Ensure that prescriptions are not issued early

- When reducing a fentanyl patch, bear in mind that the lowest dose patch available is 12 mcg/hour (MED 36mg/day). Dependent on how well the patient has tolerated previous reductions, for the final tapering step, you may wish to consider advising that they cut a 12 mcg/ hour matrix patch in half. Please note this only acceptable if they are prescribed a matrix patch

- Agree the frequency of monitoring and how this will be done with the patient. For example: arranging monthly follow-up appointments, with a telephone call after the first 2 weeks

Monitoring progress

- Check whether the patient has been able to adhere to the tapering plan and whether there has been any change in usual pain/ function and whether they have experienced any withdrawal symptoms

- Offer advice on managing pain flares and / or withdrawal symptoms if needed (see below)

- Offer encouragement for their progress so far and remind them of their reasons for tapering

- Re-evaluate whether a patient is ready to take the next step in their tapering plan and what support is required

Dealing with increased pain and/or withdrawal symptoms

- Tapering may be paused to allow time to overcome symptoms of withdrawal or worse pain before the next dose reduction

- However, tapering should not be reversed except in exceptional circumstances

- Do not be tempted to treat withdrawal symptoms with more opioids or benzodiazepines

- Reassure your patient that persistent pain varies over time, as it most likely did prior to them starting the opioid taper, and any increase following dose reduction is likely to be temporary

- Remind them why they decided to make changes to their opioid medicines in the first place, and the potential benefits of tapering for them

- Encourage patients:

    - to be kind to themselves,

    - to make time to do the things they find enjoyable and/or comforting and soothing,

    - to consider taking some gentle exercise,

    - to get support from friends or family **(see training manual section 3.2.4, *Set-back planning*)**

- Signpost to videos of patients who have successfully reduced opioids that they may find inspiring **(see training manual section 4.5, *Patient information resources*)**.

3.1.2 Optimising non-opioid pain medicines

Whilst patients may be willing to consider reducing ineffective opioids, they may expect to be offered an alternative medicine for their pain. However, for the majority of patients with persistent pain and especially those who have already been prescribed regular opioids, it is unlikely that there will be an appropriate non-opioid analgesic you can offer as an alternative. Therefore, it is anticipated that most patients attending PROMPPT reviews won't be prescribed a new analgesic.

Nevertheless, it makes sense to review the effects of their current non-opioid pain medicines at the same time as reviewing opioids. In doing so, you are:

- acknowledging the understandable and natural desire patients have to find a medicine to reduce their pain,

- providing an opportunity to enquire about what they have tried in the past and the response, so that patients can reflect on how well (or not) taking pain medicines has worked for them so far,

- gathering all the information you need in order to advise on whether there are any other options they could try and,

- creating an opportunity to address co-prescribing that is a cause for concern, for example opioids combined with gabapentinoids and/or benzodiazepines, and continued use of other ineffective pain medicines

Considering alternative non-opioid analgesics

Overprescribing of analgesics for persistent pain is often fuelled by clinicians assuming that evidence of effectiveness for one specific pain condition might imply effectiveness for persistent pain more widely. In reality, most medicines don't work for most patients with persistent pain and a few work for some patients. Prescribing for persistent pain should therefore be evidence based for the type of persistent pain problem the patient has. The indications for prescribing various groups of pain medicines are outlined below.

Paracetamol

Paracetamol is an effective analgesic for mild to moderate acute pain. It has a synergistic effect with opioids in the management of acute pain and therefore is often used in combination with opioids for its 'opioid-sparing' effect.

Current clinical guidelines consistently recommend paracetamol as the first-line analgesic medicine for pain associated with osteoarthritis, given its low risk of substantive harm (NICE Guidance, 2014). However, paracetamol provides only minimal improvements in pain and function for people with hip or knee osteoarthritis (Leopoldino, et al., 2019). There is little evidence to suggest that paracetamol is effective for other types of persistent pain and neither is there evidence that it is ineffective. However, there are concerns regarding side effects (Nice Guidance, 2016) (Robert, et al., 2015), which need to be balanced against benefit on an individual basis.

If patients are already taking paracetamol, within recommended dose limits, and feel that they benefit from it then there is no reason to change this, but it should not be continued if there is no evidence of benefit (NICE Guideline, 2020) due to the possibility of causing harm.

Topical Treatments

Topical NSAIDs should only be considered for localised joint pain and if the patient has (a) not tried them already and (b) isn't also taking an oral NSAID. There is no evidence to support the use of topical NSAIDs in other persistent pain conditions.

Topical capsaicin may be considered for knee or hand osteoarthritis (NICE Guidance, 2014) and for localised neuropathic pain (NICE Guidance, 2013)

Oral NSAIDs

NSAIDs may be useful for acute pain and some patients may benefit from NSAIDs for persistent musculoskeletal pain (NICE Guidance, 2014) (Nice Guidance, 2016). There is no evidence that NSAIDs are effective for other types of persistent pain (NICE Guideline, 2020).

The guidance regarding NSAIDs will be familiar: NSAIDs should be prescribed at the lowest effective dose for the shortest possible period of time, taking into account potential differences in gastrointestinal, liver and cardio-renal toxicity, and the patient's risk factors, including age. A plan for ongoing monitoring of risk factors should be in place, and the use of gastroprotective treatment (PPI) considered.

Gabapentinoids

Gabapentin and pregabalin (gabapentinoids) should only be prescribed for diagnosed neuropathic pain conditions and not for conditions such as chronic back pain and osteoarthritis. They are recommended in the (NICE Guidance, 2013) but it is worth noting that the majority of evidence for their effectiveness is derived from populations with either painful diabetic neuropathic pain (PDNP) and post-herpetic neuralgia (PHN). Their effectiveness outside of these clearly defined neuropathic pain conditions is less certain and evidence suggests they are not effective for sciatica (Nice Guidance, 2016).

Even for patients with neuropathic pain, gabapentinoids help only around 1 in every 4 or 5 patients. Nevertheless, as with opioids, there has been a dramatic increase in prescribing of these drugs and this has been accompanied by a growing evidence of their potential for harm including overdose, dependence and misuse. As a result, from April 2019 gabapentin and pregabalin have been designated Schedule 3 controlled drugs under the Misuse of Drugs Regulations 2001, and Class C of the Misuse of Drugs Act 1971.

If you feel that a patient has clear neuropathic pain symptoms, has not yet tried gabapentinoids and wishes to do so then it is recommended that you discuss this with a GP at the practice before a decision on prescribing is made. Combining opioids and gabapentinoids increases the risk of harm and therefore decisions about gabapentinoid prescribing needs to also take into account the patient’s readiness to reduce opioids.

A more likely scenario is that you identify patients who are continuing on gabapentinoids without benefit. In these circumstances it is appropriate to consider tapering these drugs at some point, **see section on deprescribing below.**

Antidepressants

Amitriptyline & Duloxetine are recommended by NICE as 1st-line treatments in the NICE Guideline on Neuropathic Pain (NICE Guidance, 2013). As noted above, the majority of evidence for their effectiveness is derived from populations with either painful diabetic neuropathic pain (PDNP) and post-herpetic neuralgia (PHN).

There is evidence indicating that antidepressants (duloxetine, amitriptyline and the SSRIs fluoxetine, paroxetine, citalopram and sertraline) may improve quality of life, pain and

psychological distress in some people with primary chronic pain, although the body of evidence is small (NICE Guideline, 2020). This is an off-label use of antidepressants and should not be considered except following discussion with a GP at the practice and/or on specialist recommendation.

When prescribed for persistent pain, a two-month trial of SSRI's and SNRI's (e.g. duloxetine) is usually required before deciding on effectiveness. Beyond that these drugs should only be continued for persistent pain if there is clear evidence of benefit. If antidepressants are prescribed for low mood then different considerations may apply. For recommendations on stopping or reducing antidepressants, **see section on deprescribing below**.

Benzodiazepines and other muscle relaxants

Guidelines from many countries have said that muscle relaxants should be considered for short-term use The evidence for this mainly came from studies on medications that are not licensed for this use in the UK. The 2009 NICE guideline on low back pain recommended considering diazepam as a muscle relaxant for short term use in people with low back pain when the paraspinal muscles are in spasm. This practice continues to some extent but the evidence base to support this particular use of diazepam is extremely small and in 2016 NICE made a research recommendation to find out if diazepam is clinically beneficial and cost effective in the management of acute low back pain. Since then a randomised controlled trial, reported no additional benefit of adding diazepam to NSAID therapy for acute back pain (Friedman, et al., 2017).

Benzodiazepines are not recommended for sciatica as there is evidence that they do not help this condition. Neither is there any evidence that other muscle relaxants such as Baclofen are effective (National Clinical Guideline Centre, 2016).

Benzodiazepines and other muscle relaxants are not recommended for long-term use or for chronic pain (NICE Guideline, 2020). Nevertheless, it is not uncommon to encounter patients prescribed both opioids and benzodiazepines long-term. In these circumstances, it is appropriate to consider tapering benzodiazepines at some point, **see section on deprescribing below.**

Cannabis-based products

Cannabis-based products are currently not recommended for persistent pain due to a lack of evidence supporting their use. Where trials have demonstrated benefits of cannabis-derived medicines for persistent pain, the effects were comparatively small and not cost effective. Importantly no reduction in opioid use was found (NICE Guidance, 2019). These products are not currently prescribed in primary care or in specialist pain services.

Deprescribing non-opioid analgesics

Patients with persistent pain often take a number medicines for pain, which may also be ineffective and /or potentially harmful. Of particular concern is co-prescribing of other

potentially sedating medicines such as gabapentinoids, benzodiazepines, Z-drugs for pain and/or mood/ sleep. This increases the risk of opioid-related harm considerably and increases the likelihood of opioid misuse.

It is recommended that only one change to pain medicines is made at a time. The first priority of PROMPPT is opioid tapering, in patients who agree to this. For these patients changes to non-opioid medicines can be added to the plan at a later stage.

Where patients are not ready/ willing to reduce opioids, or where this does not seem necessary (i.e. low dose, functional benefits outweighing any adverse effects/ risk) then deprescribing of other ineffective/ potential harmful pain medicines can be considered at an earlier stage.

As with opioids, benzodiazepines and gabapentinoids should not be stopped abruptly or reduced too quickly as this may precipitate withdrawal symptoms. Some patients may also experience withdrawal effects when coming off antidepressants. For this reason, gradual reduction (tapering) is recommended whenever a plan to come off gabapentinoids, benzodiazepines and antidepressants is agreed.

Gradual reduction of any potentially ineffective pain medicines is also recommended to allow for any previously unnoticed benefits to emerge. This approach also offers the opportunity to continue at the lowest effective dose, if it transpires that there is some benefit.

Gabapentinoids

- Discuss the rationale for deprescribing e.g. lack of effectiveness and/or potential risks of continued use including sedation and increased risk of falls or accidents, risk of dependence/addiction and risk of overdose (unintentional / intentional) especially in combination with opioids. Emphasise potential benefits of reducing / stopping e.g. improved alertness, concentration & memory and less prone to falls

- Discuss withdrawal symptoms and how the risk of these will be managed:

  If gabapentinoids are reduced suddenly or stopped abruptly patients may experience withdrawal symptoms including: nausea, dizziness, headaches, insomnia, restlessness and anxiety.

  Bear in mind that the patient may have experienced these in the past due to stopping the drug or missing doses (intentionally or unintentionally) and it is useful to enquire about this.

  Explain that withdrawal symptoms are unlikely to occur with gradual tapering.

- Agree a tapering plan

  Although the product characteristics of gabapentinoids suggest they can be reduced fairly quickly, over about a week, to avoid withdrawal symptoms, a slower taper is recommended. For example:

  Pregabalin: reduce the daily dose at a maximum of 50-100mg/week.

Gabapentin: reduce the daily dose at a maximum rate of 300mg every four days or so.

Benzodiazepines

For patients who have been prescribed benzodiazepines long-term, it is recommended that you liaise with the patient's GP before commencing deprescribing. Otherwise, the principles are similar to those for other potentially dependence-forming prescription medicines.

- Discuss the rationale for deprescribing including lack of long-term efficacy and potential risks of continued use including daytime sedation, falls and accidents, physical dependence, memory disorder. Risks increase in older people. Emphasise potential benefits of reducing / stopping e.g. improved alertness, concentration & memory and less prone to falls.

- Discuss withdrawal symptoms and how the risk of these will be managed:

  Possible benzodiazepine withdrawal symptoms include insomnia, anxiety, irritability, sweating and gastrointestinal symptoms such as diarrhoea. Reassure that these are temporary, lasting for days to a few weeks, and are usually mild. Explain that the dose will be tapered gradually to reduce the risk of causing withdrawal symptoms.

- Agree a tapering plan: Have a look at the algorithm for benzodiazepines and Z-drugs that has been approved by NICE. In summary this recommends a slow taper, reducing the dose by approximately 25% every 2 weeks and slowing to a roughly 12.5% reduction, if possible, and/or introducing drug-free days towards the end.

-

Antidepressants

It is now recommended that people on antidepressants are advised that if they stop taking antidepressant medication abruptly, miss doses or do not take a full dose, they may experience discontinuation symptoms such as restlessness, insomnia, unsteadiness, sweating, abdominal symptoms, irritability, anxiety, confusion and altered sensations. The severity and duration is very variable from no or mild/ self-limiting symptoms to severe long-lasting symptoms.

NICE recommends gradually reducing the dose of antidepressants, normally over a 4-week period, although some people may require longer periods, particularly for drugs with a shorter half-life (such as paroxetine and venlafaxine). This is not required with fluoxetine because of its long half-life.

For patients who have been prescribed antidepressants long-term for depression, discussion with a GP is recommended prior to considering stopping these.

Further reading about non-opioid analgesics is linked in the text above and can be found in **training manual section 4.6*, Additional learning materials.***

3.2 Supporting self-care strategies

(See also: E-learning course- PROMPPT Pain Management Skills, Supporting self-care strategies)

Patients will have adapted many of the things they do in some way to reduce the impact of their pain. Some of the strategies will be of some benefit to them, but some will come at a cost. In this section, we outline some examples of the strategies that patients take and then outline how you can support patients to pace, get active, and plan for setbacks.

Listen for signs that a patient has already adjusted some activities in order to reduce the impact of their pain, table 3.1 provides a summary of some of the self-care strategies patients may talk about.

- What steps have your patients taken to adjust to living with their pain?
- Can you think of examples where the strategies patients have adopted have been helpful and where they have been adopted at a cost?

Use reflections to help patients recognise where they use their own personal resources, abilities and skills to helpfully adjust to living with pain and validate what they are already doing, with the aim of 'building on success'. Listen out also for signs that a patient's self-care strategies come at a cost, for example making life more restricted, and reflect on this with them too.

Table 3.1. Strategies patients living with persistent pain use to help them manage their activities of everyday living

Strategy*	Examples
New ways of doing things	*"Rather than standing, I now sit on a stool to shave in the morning."* or *"I use a trolley to lean on and it makes my weekly shop a little easier."*
Doing things differently	Taking breaks: *"I've got a walk I take most mornings and there is a bench where I take a good 5 minutes break before I make my way back."* Simplifying an activity: *"I used to prepare all the vegetables myself, but now I buy those pre-prepared packs."* Avoiding an activity:

	"I don't do those things anymore, they just make my pain worse."
Planning their time	As a way of getting things done: *"If I make sure I take breaks in the morning, then I'll be able to cook dinner in the evening, you know I kinda pace myself."* As a way of saving energy: *"If I know I've got a big day coming up, I won't do anything in the day or so before and after it, that way I know I'll be able to enjoy myself more."*
Prioritising	Recognising what is really necessary: *"I just don't hoover everyday any more, it will wait."* Re-prioritising: *"Work used to be everything but now I'd rather spend my time with my family"*
Getting control	Receiving help from others: *"I ask my husband to do it now, it's easier for me that way."* Understanding that it is not possible to take part in all activities: *"I don't pick the grandchildren up any more, they know that but we have more time to sit down and have cuddles now and that works better for all of us."*
Mixing things up	Varying the intensity of an activity to get things done: *"I sit down now to have my lunch and a pause and that means I then feel refreshed later on."* Incorporating a relaxing activity into the day: *"I have a bath at night, the kids are in bed and it's my "me" time."*
Distraction	Using a joyful activity as a break away from pain: *"When I've got a really good book I can take my mind off the pain."*

*Strategies are adapted from (Kallhead & Martensson, 2018).

A useful metaphor is to think in terms of a self-care toolkit. A really useful toolkit has a number of tools, for different jobs, some may be more useful than others but they all have their place in the kit.

3.2.1 Goal setting and action planning

Having introduced goal setting and action planning in the Foundation Course **(training manual section 1.2.1, *Persistent pain and the role of self-management*)** you will now be familiar with the two types of goals relevant to the PROMPPT consultation, the first being related to changes in pain medicines (opioid goals) and the second related to pain self-care (self-care goals). You will also be familiar with the concept of a values-based goal and how to elicit a values-based goal **(see training manual section 2.8, *Shifting the conversation to self-care*)**, that may help the patient move in the direction that is important to them.

This section outlines how patients can be supported to achieve their goals before describing how progress can be measured and how to support a patient to get started with an action plan in the context of the PROMPPT consultation.

Getting support with an action plan

To help patients achieve PROMPPT goals they can be supported emotionally by their support networks and structurally in terms of the set-up of their appointments and by the information they receive at the time of their appointment:

Emotional

- Ask the patient who they can talk to, to get support to work towards goals
- Ask whether it would be useful for patients to share PROMPPT resources with friends or family and/or attend PROMPPT appointments with them

Structural

- Ask what type of follow-up they would prefer and how often (brief telephone consultation, video, or if available face-to-face)
- Ask the patient whether they would prefer to make dose changes when their prescriptions are issued or whether they would be comfortable and/or prefer to make a change of dose in their own time

Informational

- Ask the patient whether they would prefer either paper or electronic PROMPPT resources
- Write the goal and action plan in the PROMPPT review plan as a reminder

Measuring progress

Goals can be of any duration, from a week or two, one month or even longer and it is common practice to set short- mid and long-term goals. Not all these steps or goals need to be explicitly written down if that doesn't feel appropriate, but for complex cases whereby progress is likely to be slow this might be an effective way of measuring progress as well as communicating with the wider healthcare team.

Measuring the progress of an opioid goal

In terms of an opioid goal, whereby you might be moving in the direction of reducing pain medicines to the lowest effective dose, progress can be evaluated by a reduction in strength and/or frequency of a regular or as-required dose.

Measuring the progress of a self-care goal

In terms of a self-care goal, the quantity of a continuous activity (for example, distance walked, lengths swum) or frequency (for example, number of times an activity is completed in a week) is often evaluated.

Getting started with an action plan

Often getting started is the hardest of steps to take. For those patients who are ready to make some changes, it's really useful to have a conversation about getting started and asking:

> *When can you see yourself getting started [with that change to your medicines/ making that phone call to your friend]?*

For patients who are still contemplating a change and with whom you've had a conversation about a future plan you could still ask the same question, but the response may be "you know, I'm not ready yet, but I'm going to sort x and y and z out and then can I come back and talk to you?".

3.2.2 Pacing

By now you will understand that patients will adjust to living with pain in different ways. Sometimes the adjustments that patients make will come at a cost. The key is to get an overall impression of whether they are still engaged in a full and meaningful life and whether the strategies they have adopted help them to move in that direction.

Compare the following examples of steps patients have taken to adjust to living with pain:

"I don't hoover everyday anymore and then I don't get the pain so much"

"I hoover all of the house but then I pay for it"

"I just don't hoover everyday anymore, it will wait and then I'm less snappy with my husband, it's just that I have more energy to do things with him"

The first two examples seem to come at a cost when compared with the third. When the strategies that patients have taken on board seem to come at a cost then you might explore that with them further, with something like:

> *Overall, it sounds like you have changed the way you do things because of your pain and you avoid some activities all together but that doesn't seem to be helping you much at the moment*

However, it is important to reinforce an example of a helpful strategy, for example you could explain:

> *You've changed the way you do things like hoovering and that's helping you to do the things that matter to you like spending time with your husband.*

This may encourage patients to think about the long-term usefulness and sustainability of their current strategies and perhaps consider alternatives, if that is what is needed.

Pacing can be a useful strategy to help patients move in the direction of a values-based life and it encompasses many of the other strategies outlined in table 3.1 (such as prioritising, planning, goal setting and getting active). Like other strategies that patients take on board, pacing can come at a cost and a balanced approach is important.

Familiarise yourself with the patient information leaflet on pacing **(also available in training manual section 4.5, *Patient information resources*)**, it will help you when signposting patients to self-help resources.

3.2.3 Getting active

Discussions about getting active can be difficult. The majority of people know that exercise is good for them but patients consulting with pain may not realise that exercise will benefit them, even with pain.

The first step in a consultation is to listen out for exercise-talk; snippets of conversation where patients might mention being active, wishes or worries about being active even if it sounds quite remote. For example:

I did used to be fit...

I try and take my dog for a walk…

My daughter had mentioned a swimming class just for women…

My friend goes to yoga…

Then, whether there have been snippets of exercise talk or not, reflect on the activity they do engage with to validate their exercise behaviours and beliefs. Where there have been snippets of exercise talk, you could briefly explain some of the benefits of being active and then ask them how that sounds to them.

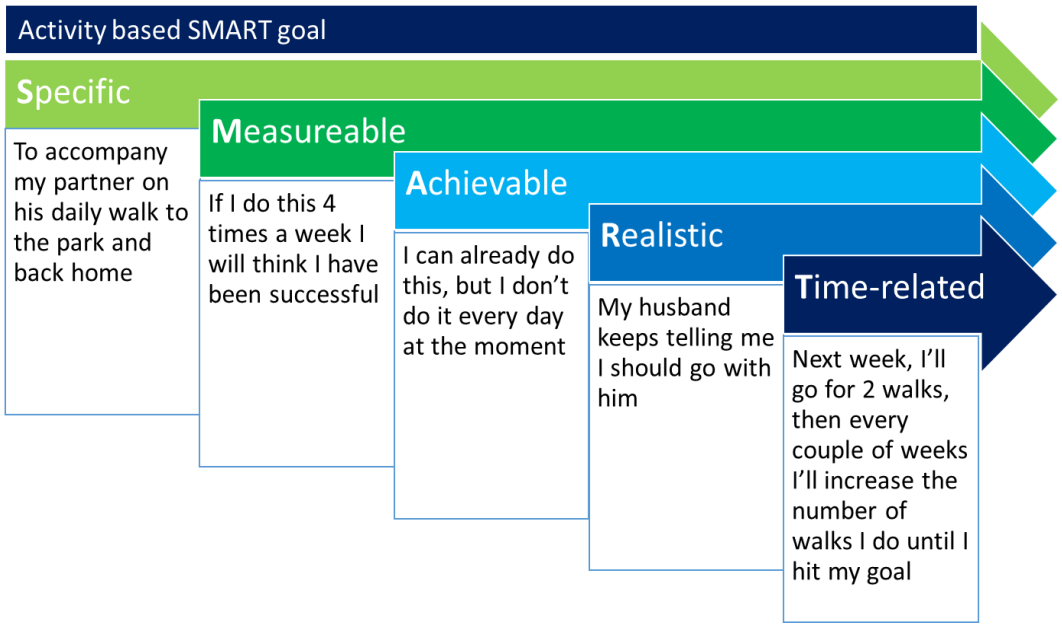
Many people with pain find that being more active helps their general well-being and can help you live better with the pain. I wonder what you make of that?

And for a patient who seems a little less ready to contemplate getting active, you could change that to:

We know that being active is helpful even for people like you who live with pain, but we know that sometimes it can be difficult to get started because pain gets in the way. How does that sound to you?

In the foundation course, we highlighted that there has been a shift away from prescribed activity as this could reinforce the idea that being active is a short term thing **(see training manual section 1.2.1, *Persistent pain and the role of self-management*)**. A better way forwards is for patients to be active consistent with their SMART goals and values (see Figure 3.1 for an example of a values-based SMART goal).

Figure 3.1 An example of a values-based SMART goal with a focus on being more physically active



Being active may be more important to some patients than others, it's important to respect this. Let the stuck patient know that you could have this conversation again at some point in the future and you could signpost them to the PROMPPT information on being active with pain **(also available in training manual section 4.5, *Patient information resources*)**.

For a patient who is ready to be more active but is unsure how to start, an explicit approach may be helpful (*ask: would it help you get started if we break this goal down a bit more?*). You could then work with the patient to identify the support they may need and ways to measure progress **(see training manual section 3.2.1, *Goal setting and action planning*)**.

3.2.4 Set-back planning

Persistent pain is often unpredictable, both in terms of location and intensity of pain and this can be frustrating and distressing for patients. Set-backs are common and often occur for no apparent reason. **Training Manual section 2.4.2, *Assessing readiness to change*** outlines how a set-back can result in momentary lapses in progress or could result in a step-back in terms of the readiness to make further changes. An important strategy is to have a set-back plan.

Patients often ask whether they can go back on a medicine or increase the dose of the medicine if they have a set-back. If this does happen, it can be of some value to validate the individual patient's concerns and to reflect on why they agreed to make a reduction in the first place. In the first few weeks of an opioid reduction some patients do experience an increase in their usual pain and some information (verbal and/or written) on what to expect may help them plan for this. A useful resource to signpost the patient to is the PROMPPT resource on what to expect in the first few weeks of reducing opioids, which is **also available in training manual section 4.5, *Patient information resources***

If a patient does have a set-back the following may be useful tips to help get them back on track:

- Reassurance that set-backs are common and part of adjusting to life with pain which can be unpredictable
- Re-evaluate whether the patient is ready to make further changes and what support is required
- Revisit and re-validate the self-care strategies (planning, prioritising, pacing, distraction, relaxation, getting help, being active) that work well for the patient and offer reassurance that these strategies are helpful
- Encourage patients
    - to be kind to themselves
    - to make time to do the things they find comforting and soothing

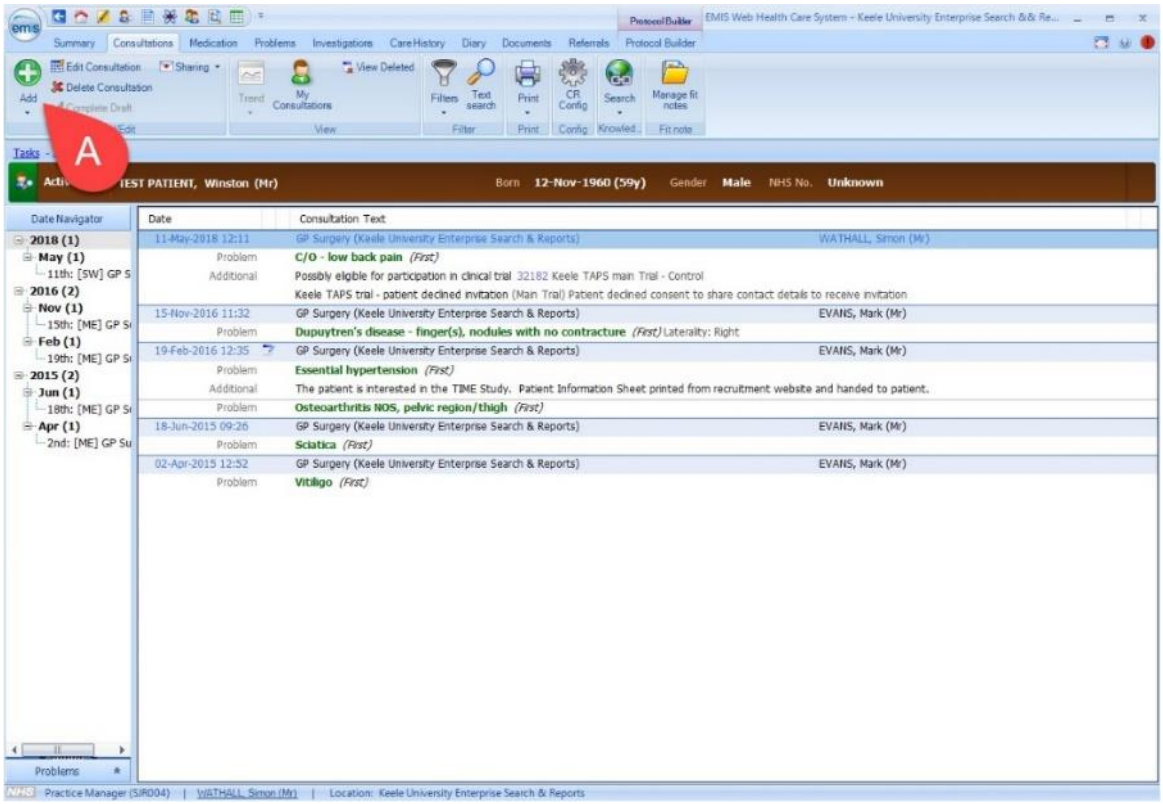
There may be a point when you agree to pause on a reduction, especially if other life stressors are placing extra demands on how they use their personal resources and this decision may be made with the GP.

3.3 Completing PROMPPT study documentation
(See also: E-learning course- PROMPPT Pain Management Skills, Completing PROMPPT study documentation)

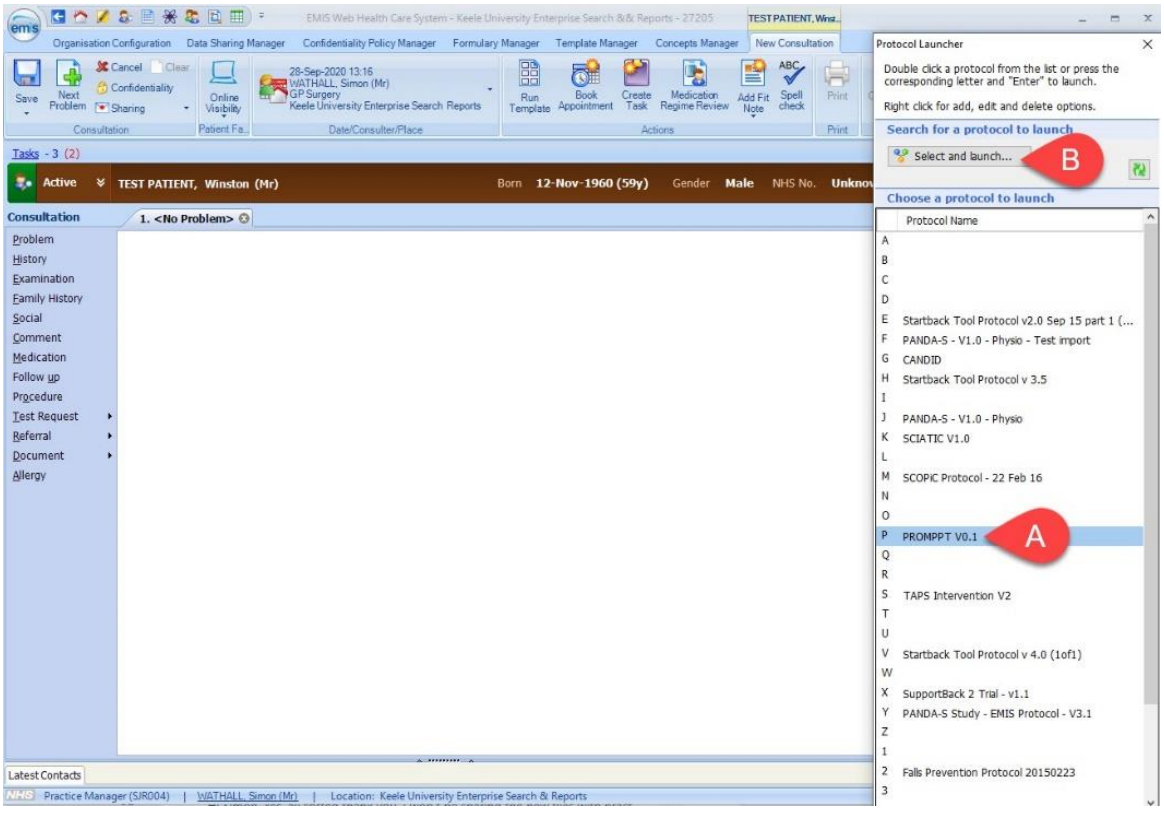
3.3.1 Finding and using study documents in EMIS and SystmOne

The following step-by step guides will help you navigate the PROMPPT documents within EMIS.

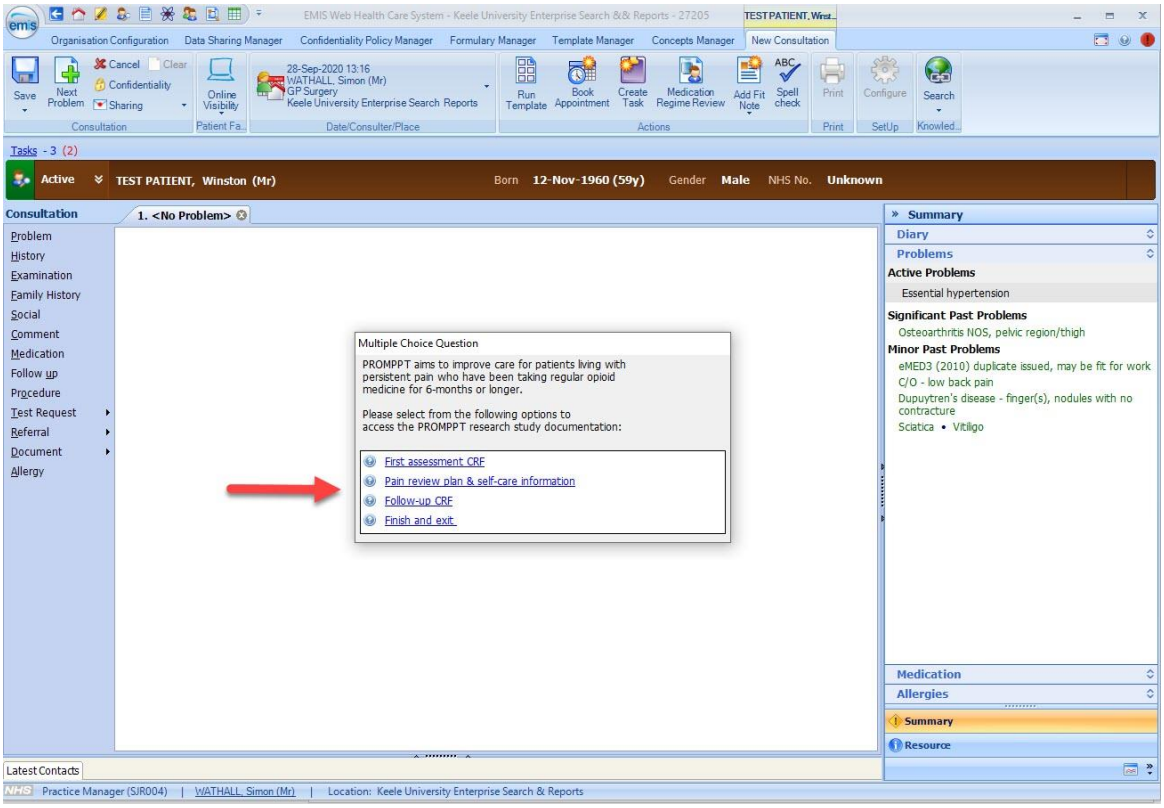
1. Access the patient's consultations list and add a consultation in the usual manner [A].



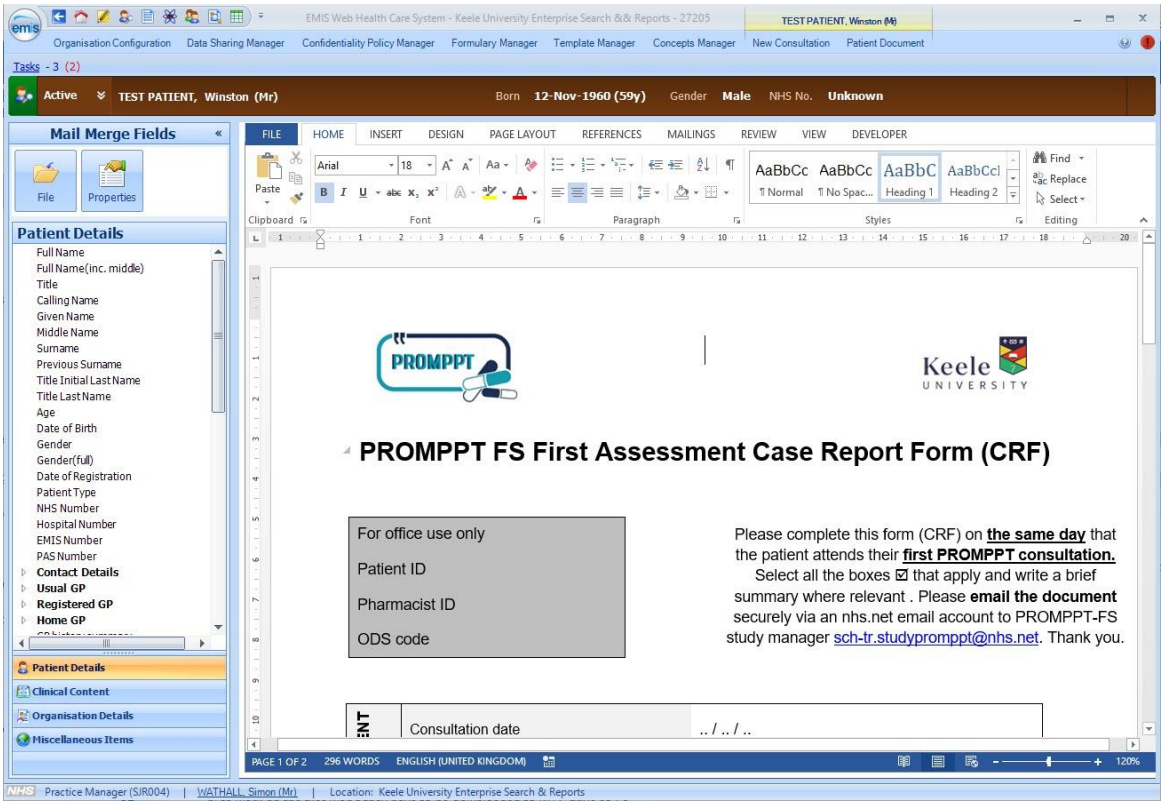
2. When in the 'new consultation' screen press F12 to activate the Protocol Launcher sidebar. Then select from the list the PROMPPT protocol [A] [This needs to be setup prior to 1st use and instructions will be provided] or [B] the Select and Launch Button to find and activate the protocol.



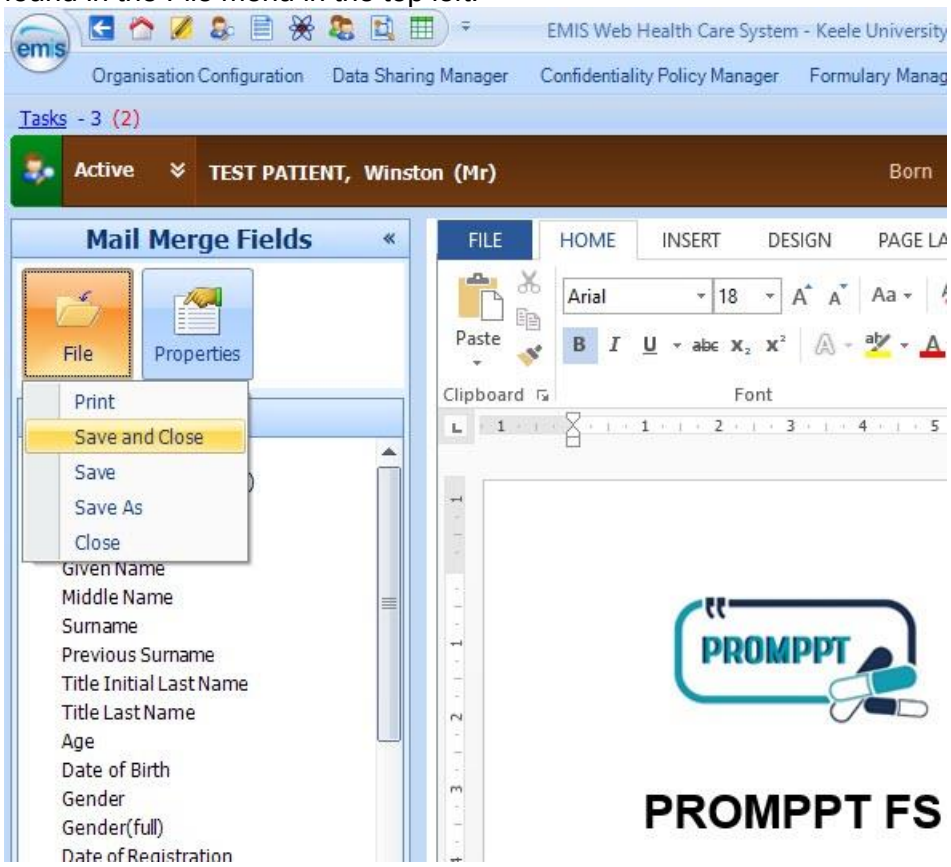
3. After activating the protocol you are presented with the menu screen whereby you can select which of the PROMPPT documents you wish to access at this time



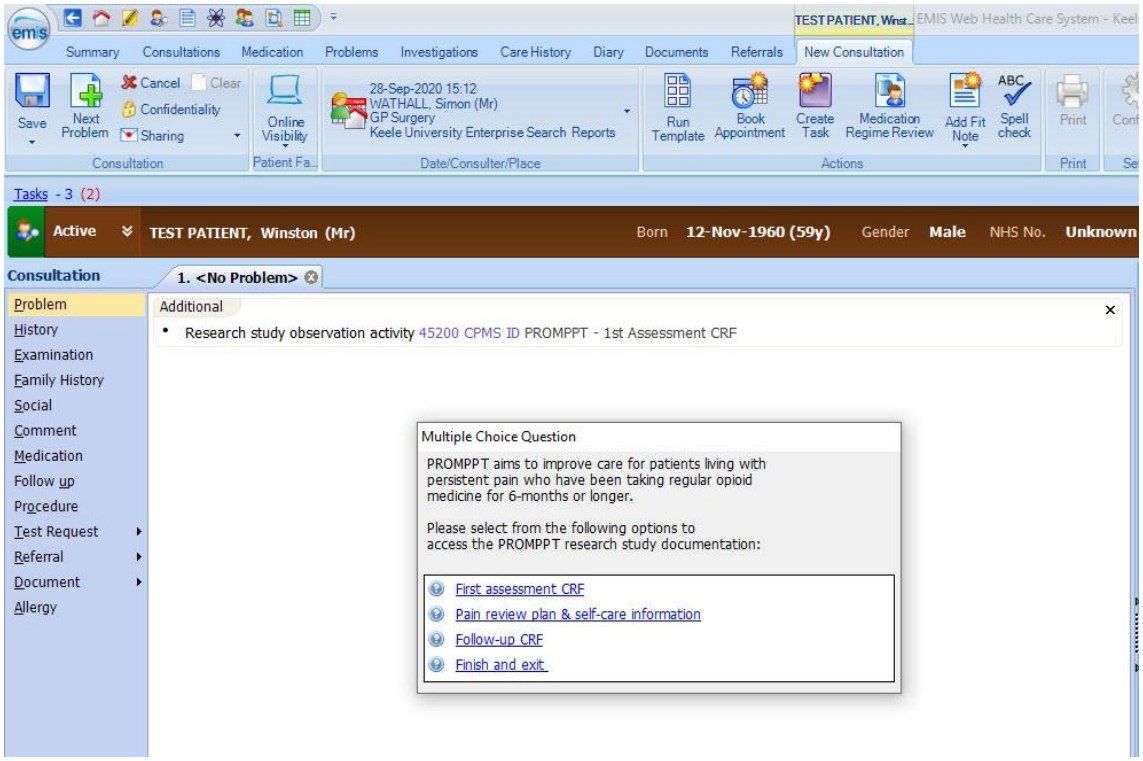
4. Select the First assessment CRF for completion.



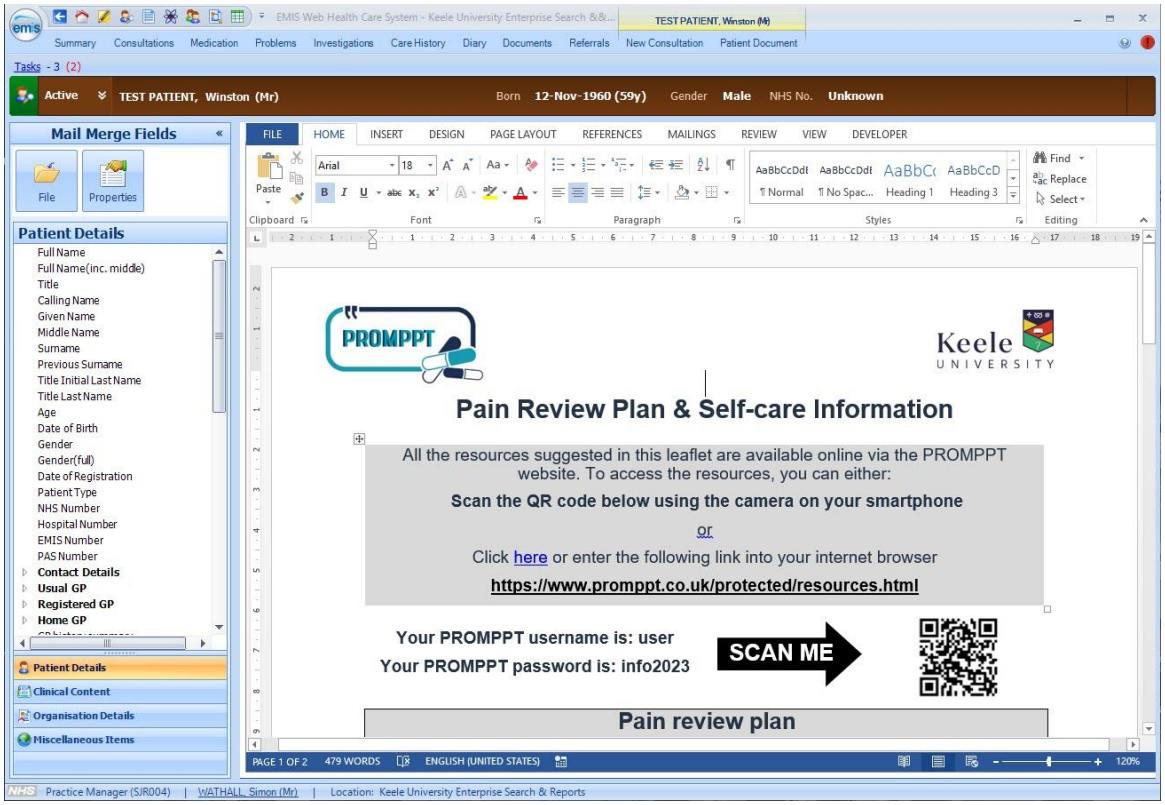
5. When you have finished completing a document always use the Save and Close function found in the File menu in the top left.

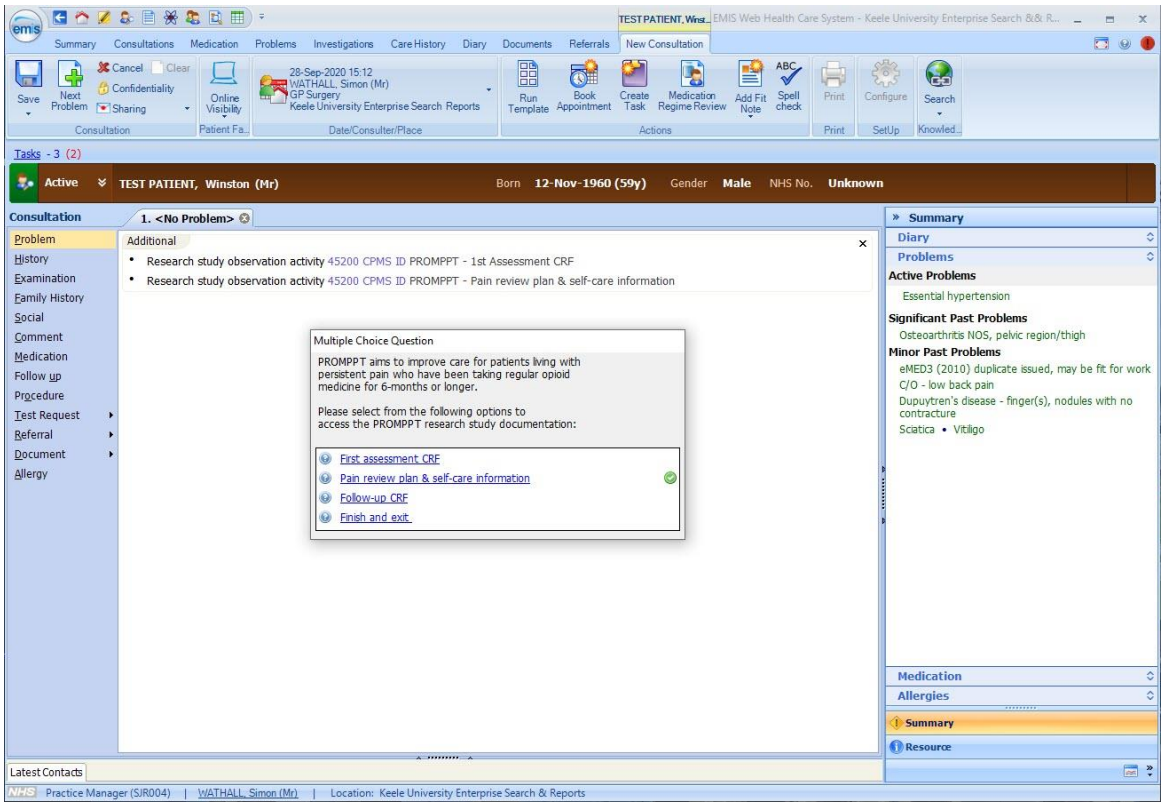


6. Once you have saved a document you will always be taken back to the main menu.



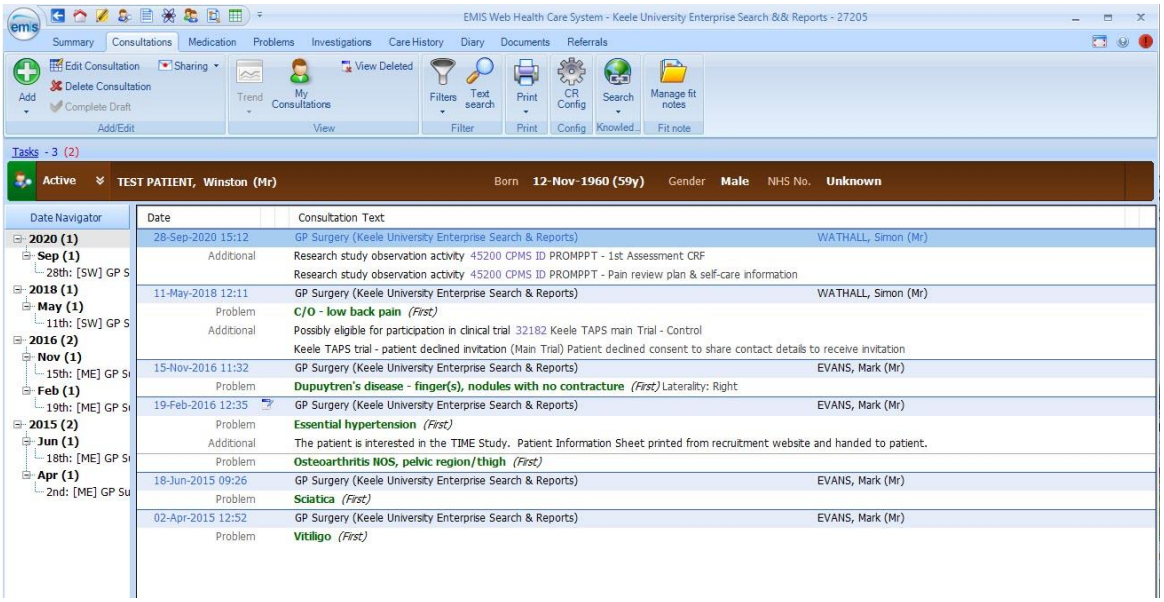
7. Select the pain review plan & self-care information for completion.



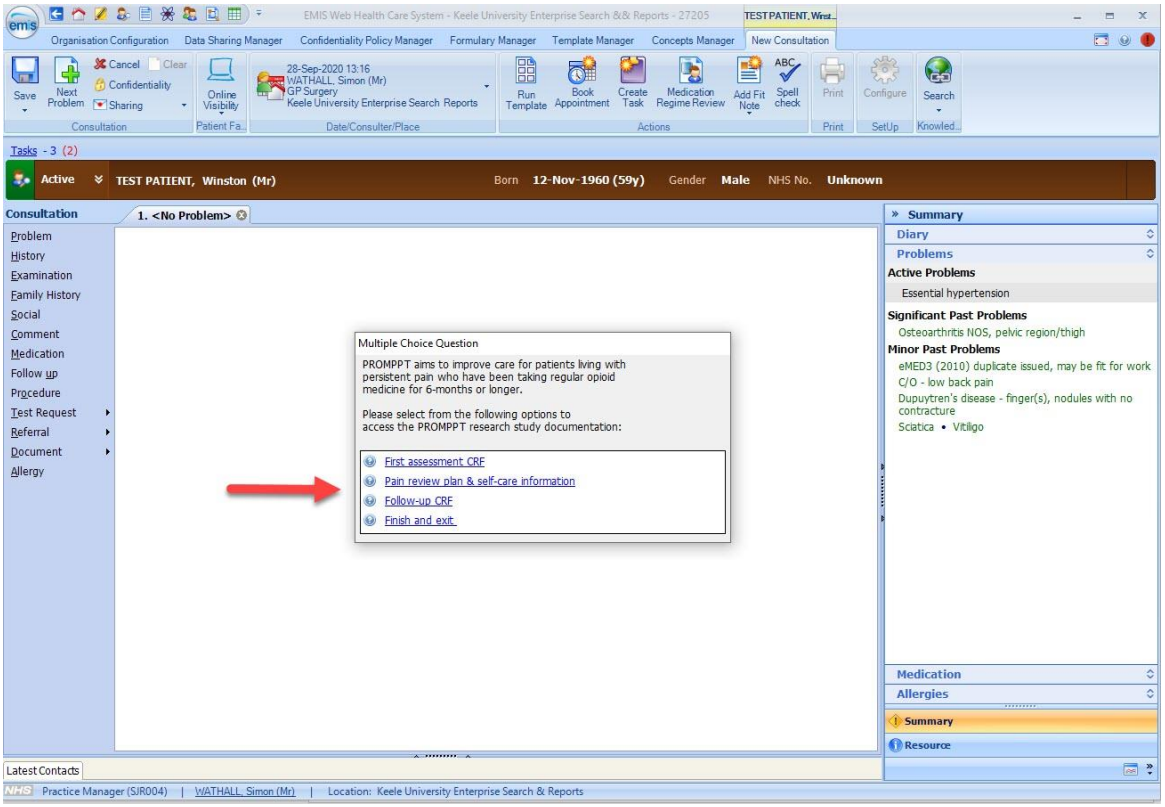


8. As you complete a document, a clinical code is added and recorded in the patient's record.

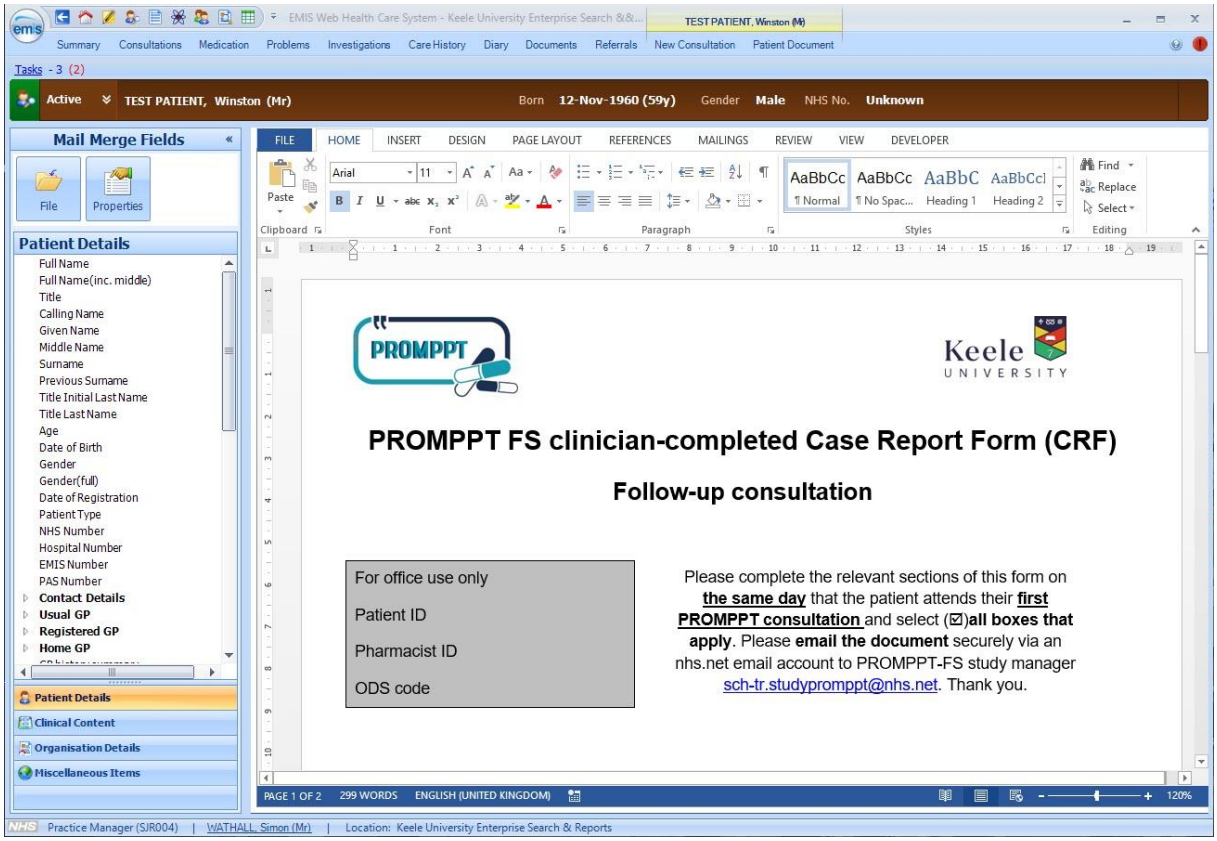
9. When you look at a patients saved consultations you will be able to see which document was used and when.



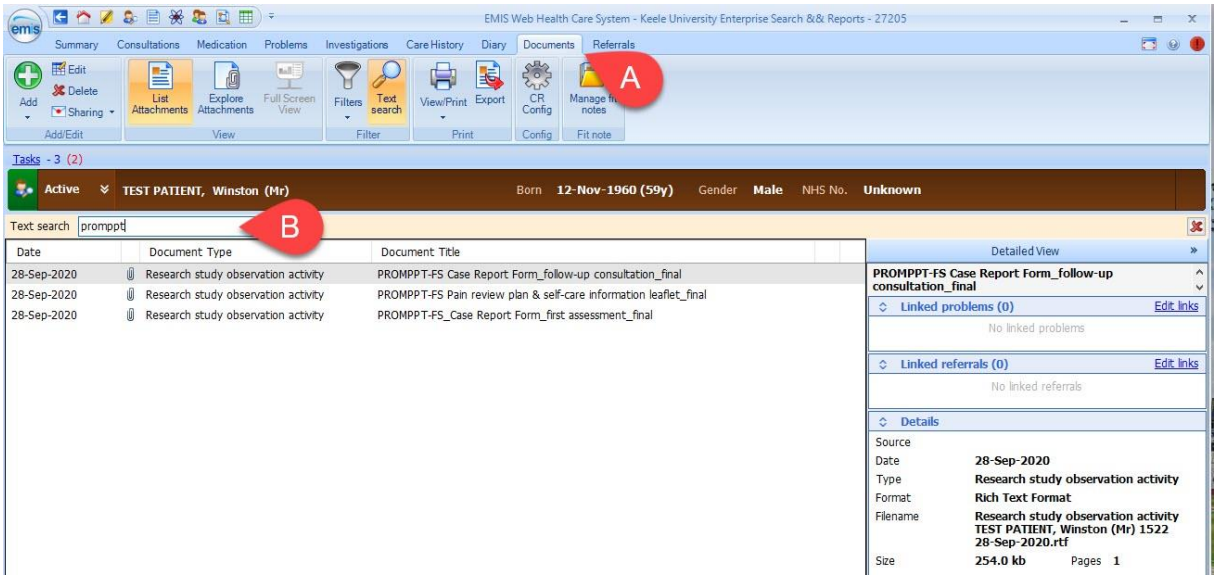
10. On subsequent follow up appointments you will repeat the process of activating the protocol but from the main menu selecting ‘Follow up CRF’.



11. Select the Follow up CRF for completion, remembering to Save and Close the document on exit.

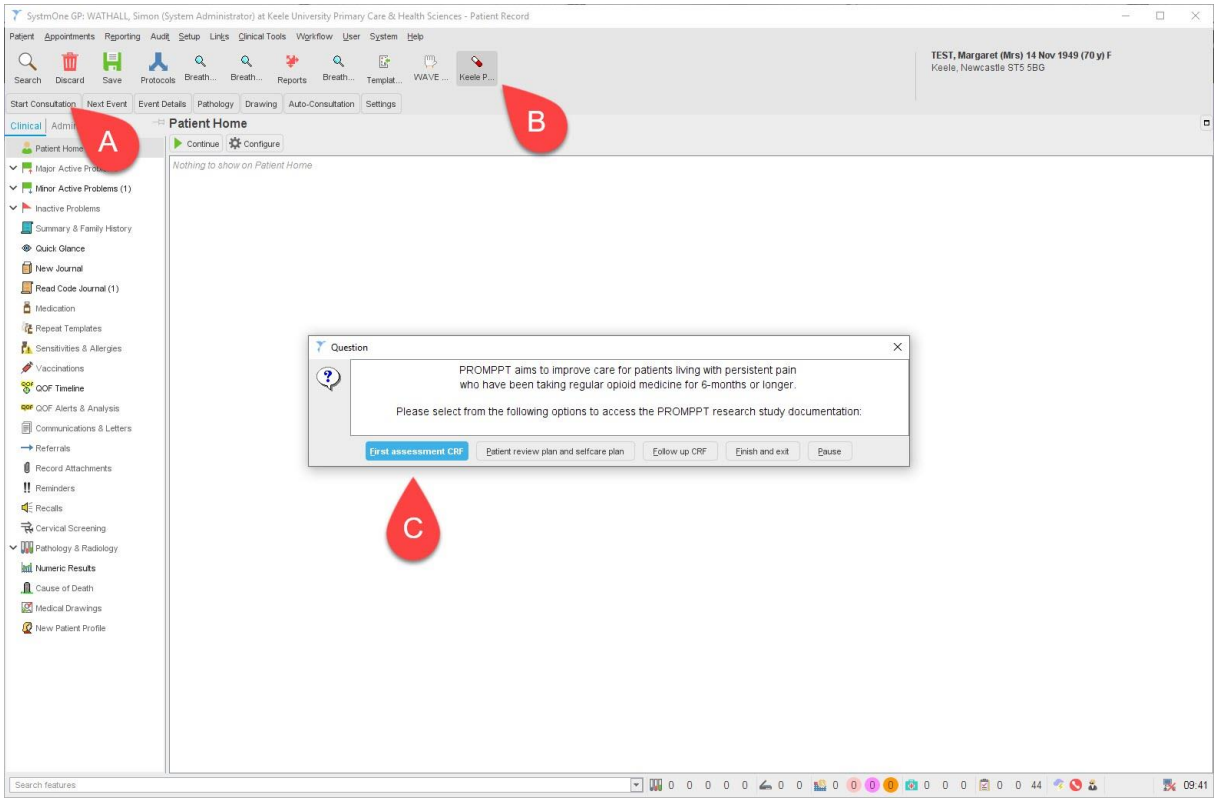


12. Any of the PROMPPT documents you save in the patient's record can be easily retrieved for editing or to print etc. by accessing the Documents tab in the patients Care Record [A]. Patients will probably have a long list of documents on their record, to easily find the PROMPPT documents, use the search bar [B].

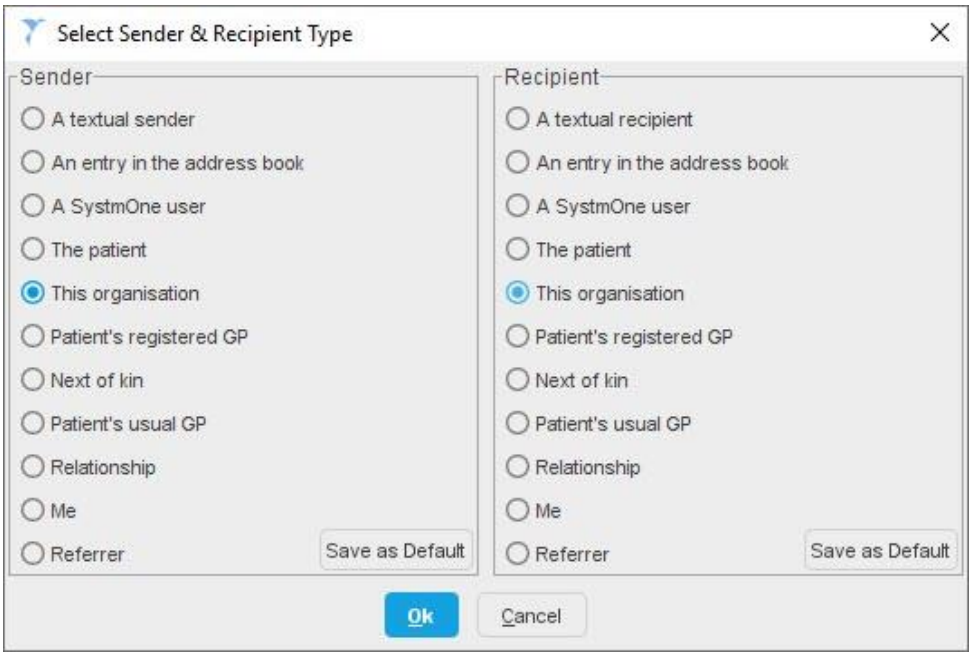


The following step-by step guide will help you navigate the PROMPPT documents within SystmOne.

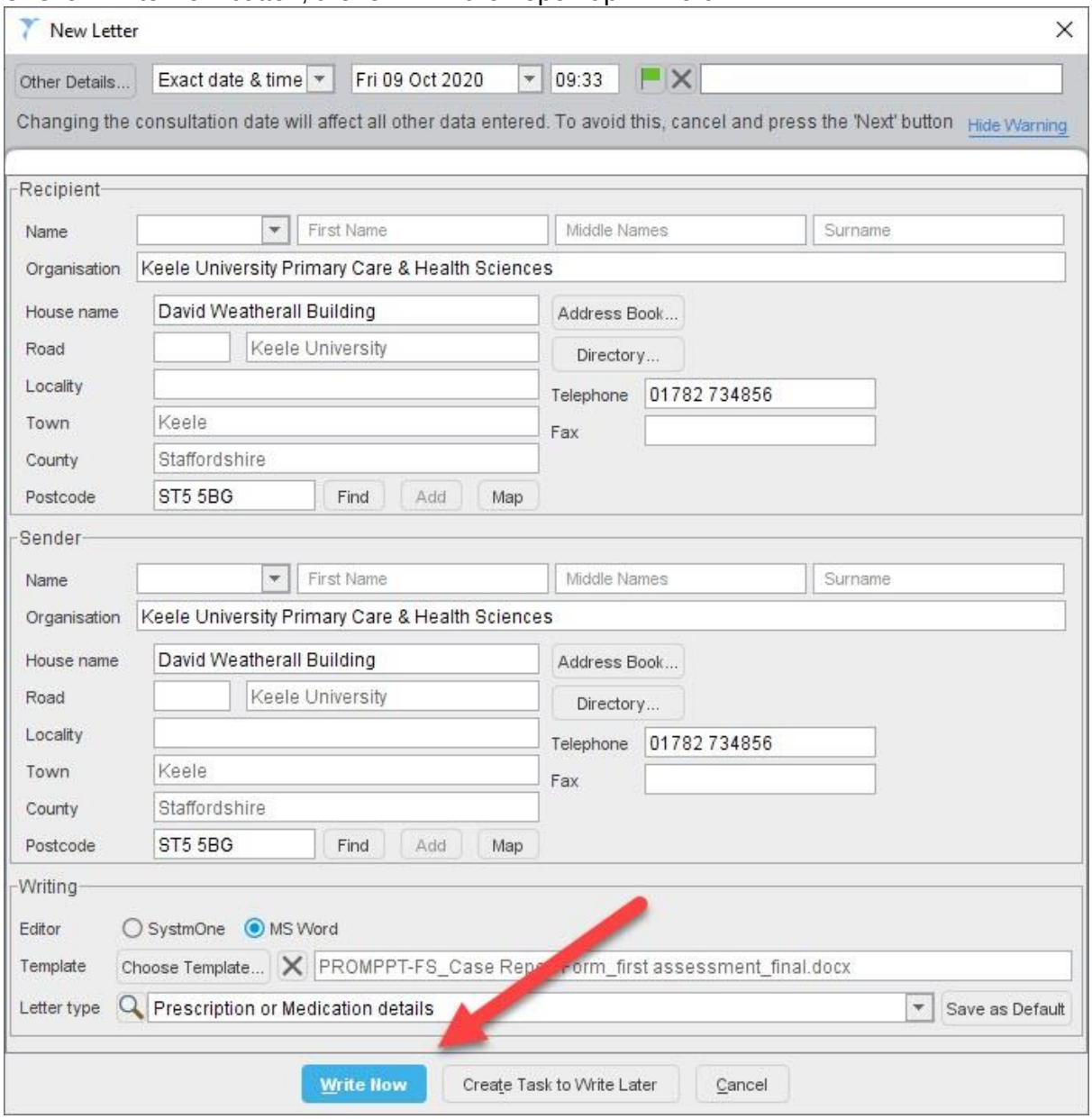
1. Access the patient's consultations list and then add a consultation in the usual manner [A]. When in the 'New consultation' screen click on the Quick Action icon previously installed on the Toolbar to activate the protocol [B]. After activating the protocol, you are presented with the menu screen [C] whereby you can select which of the PROMPPT documents you wish to access at this time. Select 1st assessment CRF for completion.



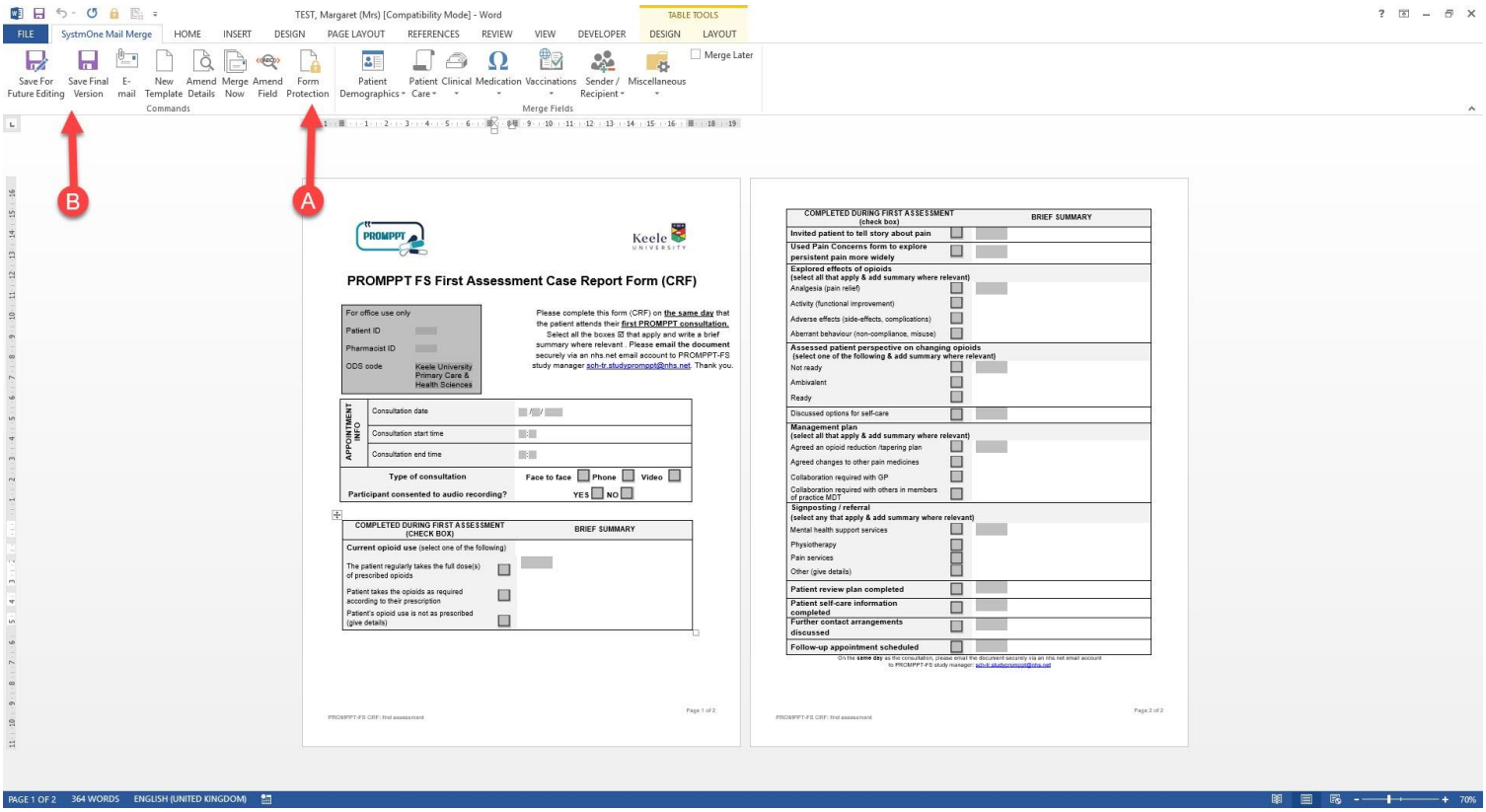
2. Select Sender & Recipient type – Both "This organisation" click ok.



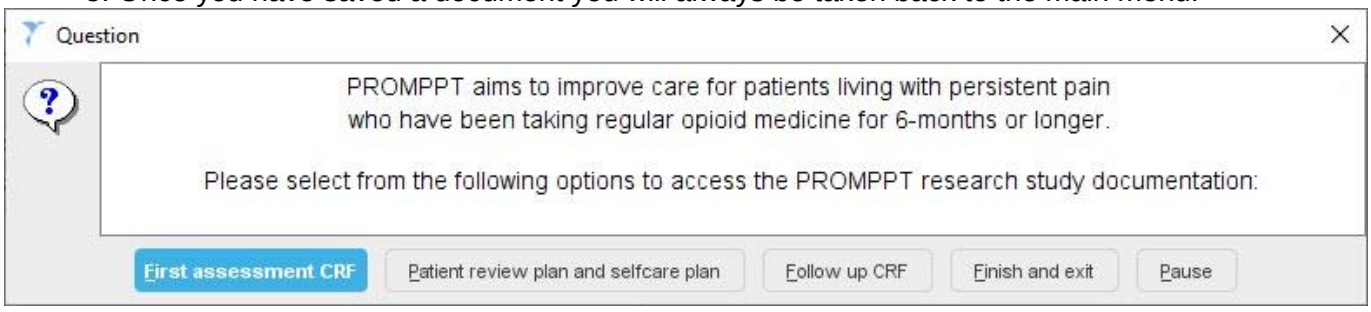
3. Click Write Now button, the form will then open up in Word.



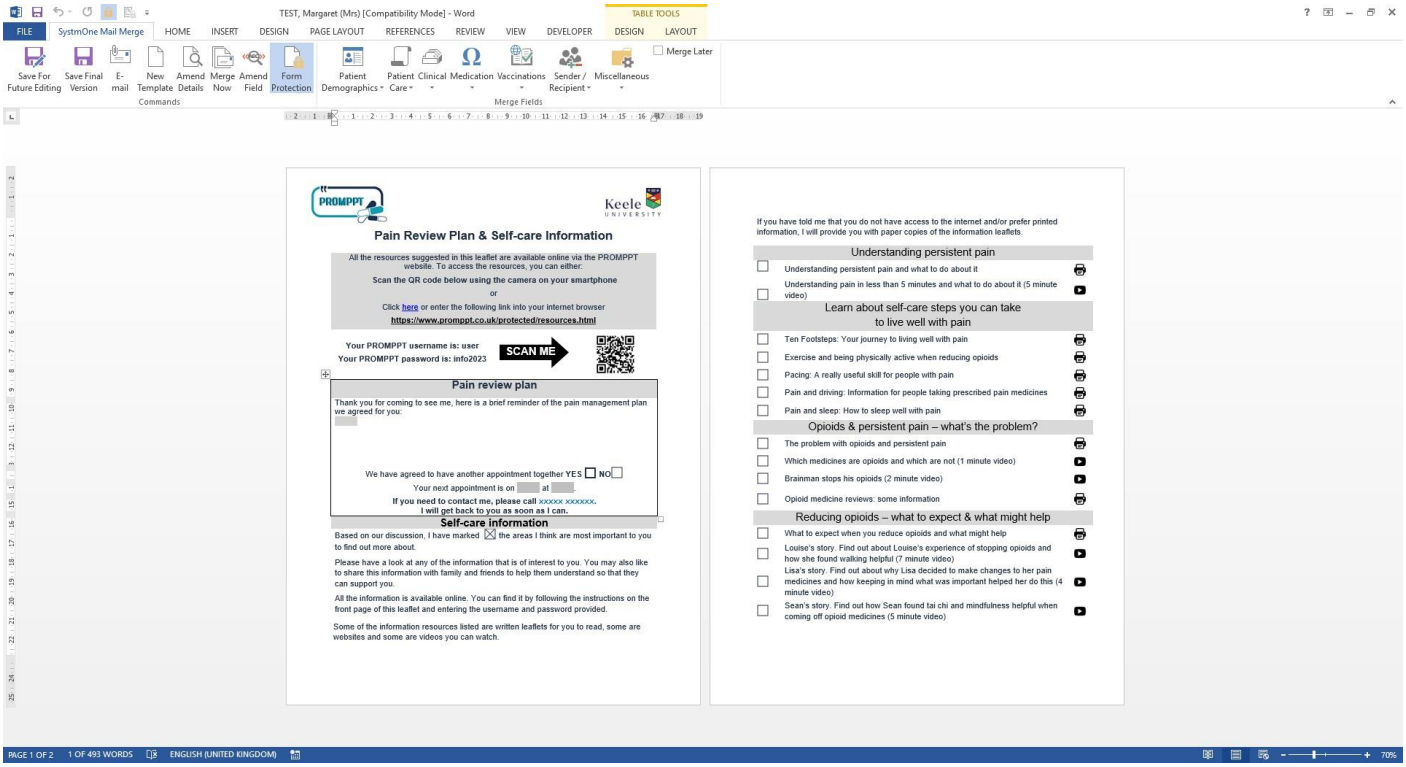
4. Click the Form Protection button [A] then complete the form fields as required. When you have finished completing a document Save and Close [B].



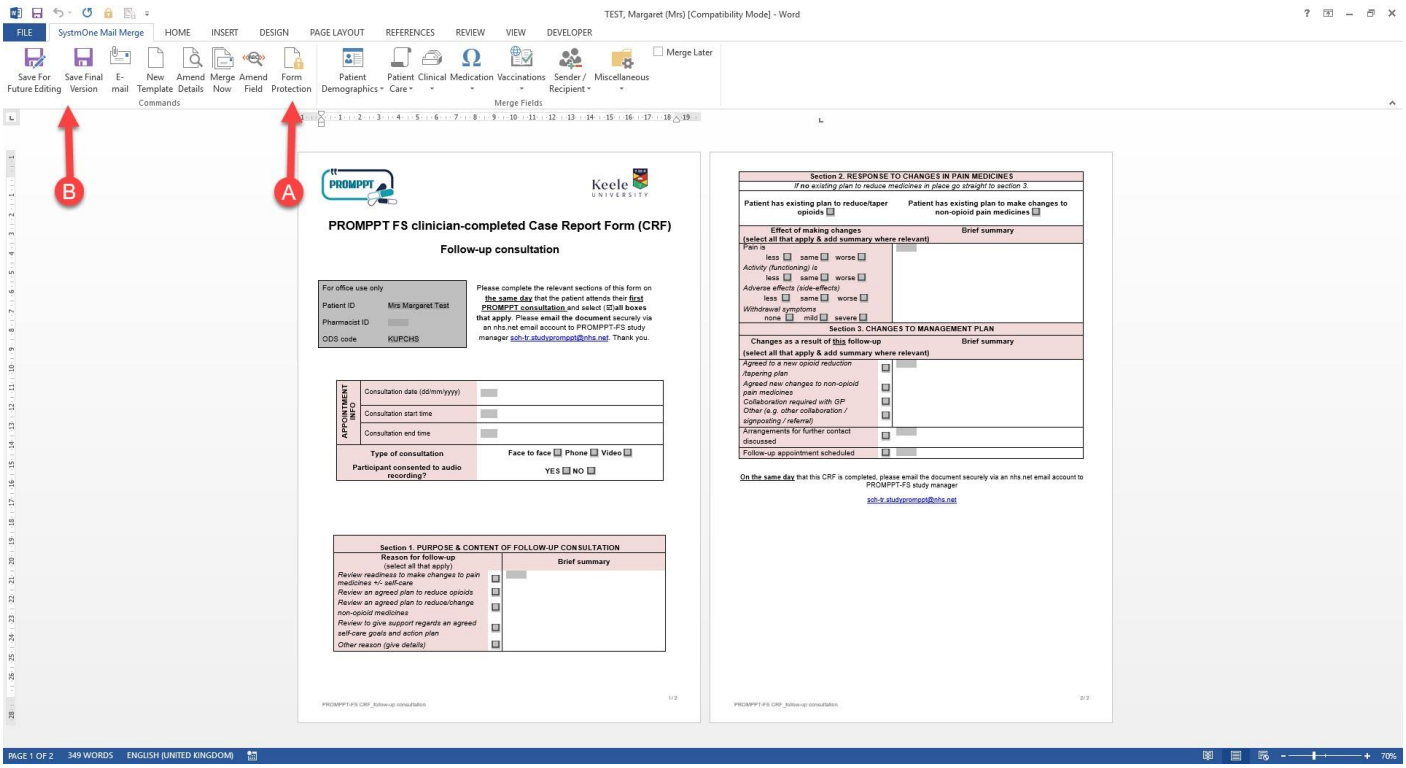
5. Once you have saved a document you will always be taken back to the main menu.



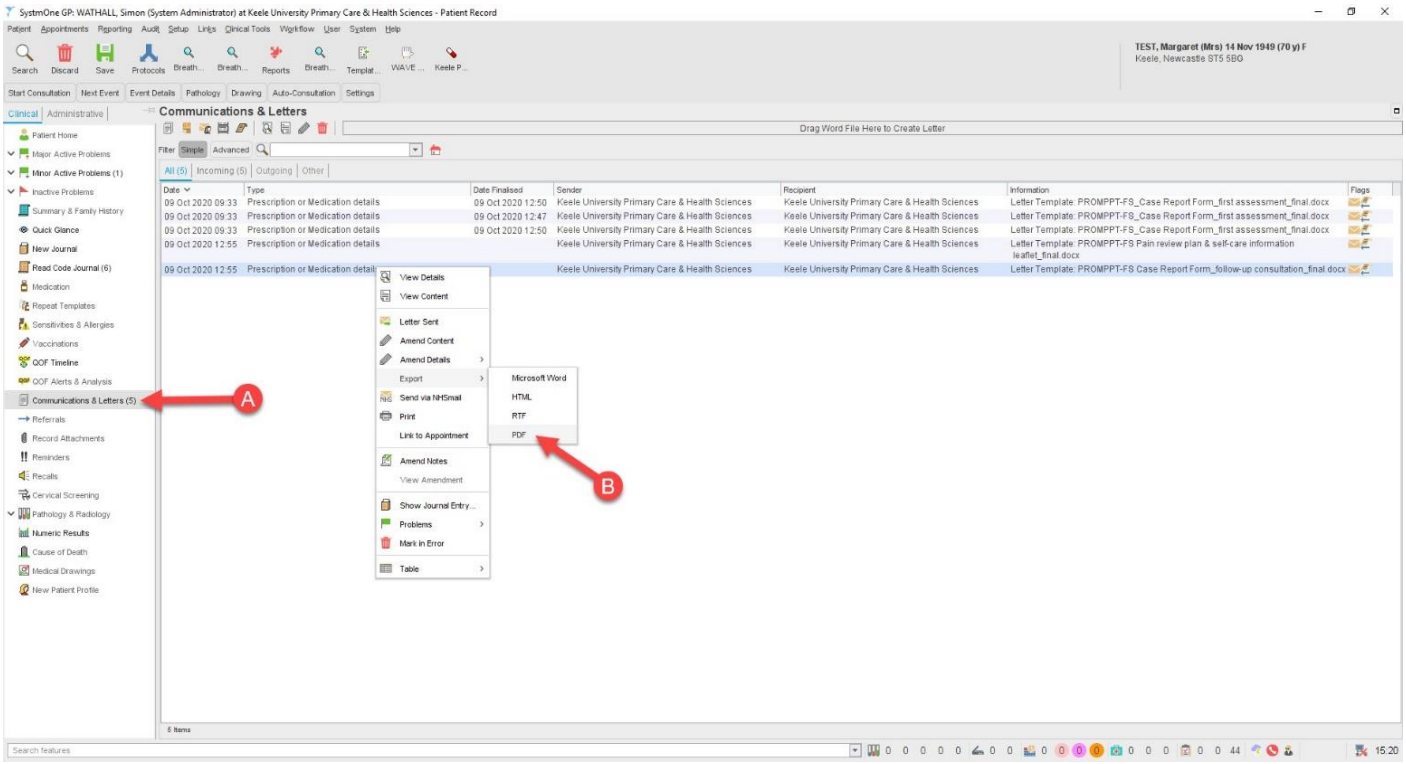
6. Pain review plan & self-care info leaflet. As you complete a document, a clinical code is added and recorded in the patients record.



7. On subsequent follow up appointments you will repeat the process of activating the protocol but from the main menu selecting 'Follow up CRF', remembering to Save and Close the document on exit. When you have finished completing the form(s) click Finish & Exit.



8.Any of the PROMPPT documents you save in the patient's record can be easily retrieved for editing or to export by accessing the Communication & Letters tab [A] in the patients Care Record. From here you are able to export the documents as a pdf for sending to the study team. Select the letter then right click, select Export then PDF [B].



3.3.2 First assessment CRF

The grey box "For office use only", will auto-populate with the patient's ID, and the practice ODS code. The Pharmacist ID may be left blank but may be used for the main clinical trial. Please complete the requested information about the appointment, the type of consultation and whether the patient agreed to the consultation to be recorded. The remaining parts of the document allow for you to record the consultation, and an example is given below for your reference. An unpopulated version of this document is available in **training manual section 4.4, *Case report forms***.

On the same day as your consultation, please email the completed CRF to the study manager (sch-tr.studypromppt@nhs.net).

Figure 3.2 PROMPPT First Case Report Form example

PROMPPT FS First Assessment Case Report Form (CRF)

For office use only
Patient ID
Pharmacist ID
ODS code

Please complete this form (CRF) on **the same day** that the patient attends their **first PROMPPT consultation.** Select all the boxes ☑ that apply and write a brief summary where relevant . Please **email the document** securely via an nhs.net email account to PROMPPT-FS study manager sch-tr.studypromppt@nhs.net. Thank you.

APPOINTMENT INFO	Consultation date	01 / 01 / 2021
	Consultation start time	14:00
	Consultation end time	14:35
Type of consultation		Face to face ☐ Phone ☑ Video ☐
Participant consented to audio recording?		YES ☑ NO ☐

COMPLETED DURING FIRST ASSESSMENT (CHECK BOX)		BRIEF SUMMARY
Current opioid use (select one of the following)		codeine 30mg x2, x4 daily
The patient regularly takes the full dose(s) of prescribed opioids	☑	
Patient takes the opioids as required according to their prescription	☐	
Patient's opioid use is not as prescribed (give details)	☐	

COMPLETED DURING FIRST ASSESSMENT (check box)		BRIEF SUMMARY
Invited patient to tell story about pain	☑	About 5-yr history of knee pain, started taking codeine when diagnosed with osteoarthritis 2-3 yrs ago
Used Pain Concerns form to explore persistent pain more widely	☑	Happy to talk about concerns, patient still active (ticked 2 boxes about feeling low, and sleep). Main worries about stopping meds.
Explored effects of opioids **(select all that apply & add summary where relevant)**		
Analgesia (pain relief)	☑	No clear pain relief (some relief, sometimes but not often), or benefit to function. Often feels sleepy through the day and then can't sleep at night, increase in weight since started taking opioids. Used to take more than prescribed, but it didn't help and it worried pt's wife- so stopped.
Activity (functional improvement)	☑	
Adverse effects (side-effects, complications)	☑	
Aberrant behaviour (non-compliance, misuse)	☑	
Assessed patient perspective on changing opioids **(select one of the following & add summary where relevant)**		
Not ready	☐	Some concerns as stopped suddenly before, but happy to try again.
Ambivalent	☐	
Ready	☑	
Discussed options for self-care	☑	Pain can get pt down but exercise helps this and knees. Keen to become more active to help lose weight

Management plan **(select all that apply & add summary where relevant)**		
Agreed an opioid reduction /tapering plan	☑	Plan to reduce daily dose codeine by 30mg, starting tomorrow (reduce mid-morning dose). Agreed for follow-up (phone) before next reduction.
Agreed changes to other pain medicines	☐	
Collaboration required with GP	☐	
Collaboration required with others in members of practice MDT	☐	
Signposting / referral **(select any that apply & add summary where relevant)**		
Mental health support services	☐	None needed
Physiotherapy	☐	
Pain services	☐	
Other (give details)	☐	

Patient review plan completed	☑	Plan as above
Patient self-care information completed	☑	Pt interested in What to expect in 1st few weeks and sean's story
Further contact arrangements discussed	☑	
Follow-up appointment scheduled	☑	Follow up in 10-days

On the **same day** as the consultation, please email the document securely via an nhs.net email account to PROMPPT-FS study manager: sch-tr.studyprompppt@nhs.net

3.3.3 Review plan

We have created a patient-facing leaflet called the Patient review plan & self-care information. In this lesson we'll outline, with some examples, how you can complete the review plan with the goals and/or action plan that you may have agreed to within a PROMPPT consultation. The full version of the leaflet is available in the **training manual section 4.3, *Pain review plan & self-care information***.

Your contact telephone number should auto-populate but you might need to check within your practice. There is space for a brief summary of the plan you agreed with the patient. In the example below, the text is written in plain English with a plan for a self-care goal and an opioid goal.

Figure 3.3 Pain review plan example 1

Pain review plan

Thank you for coming to see me, here is a brief reminder of the pain management plan we agreed for you:

- Stop your midday dose of codeine, starting from tomorrow.
- Talk to your daughter about restarting aqua class after the holidays
- We'll talk about next steps when we next have an appointment together.

We have agreed to have another appointment together **YES** ☒ **NO** ☐

Your next appointment is on Monday 01 October 2021 at 14:00.

If you need to contact me, please call 01782 000111.
I will get back to you as soon as I can.

Figure 3.4 Pain review plan example 2

Pain review plan

Thank you for coming to see me, here is a brief reminder of the pain management plan we agreed for you:

- Continue to take the pain medicines that you are currently on
- Have a look at the information that we talked about and I have ticked on the next page
- Find a chance to talk to your husband about your pain and your medicines

We have agreed to have another appointment together **YES** ☒ **NO** ☐

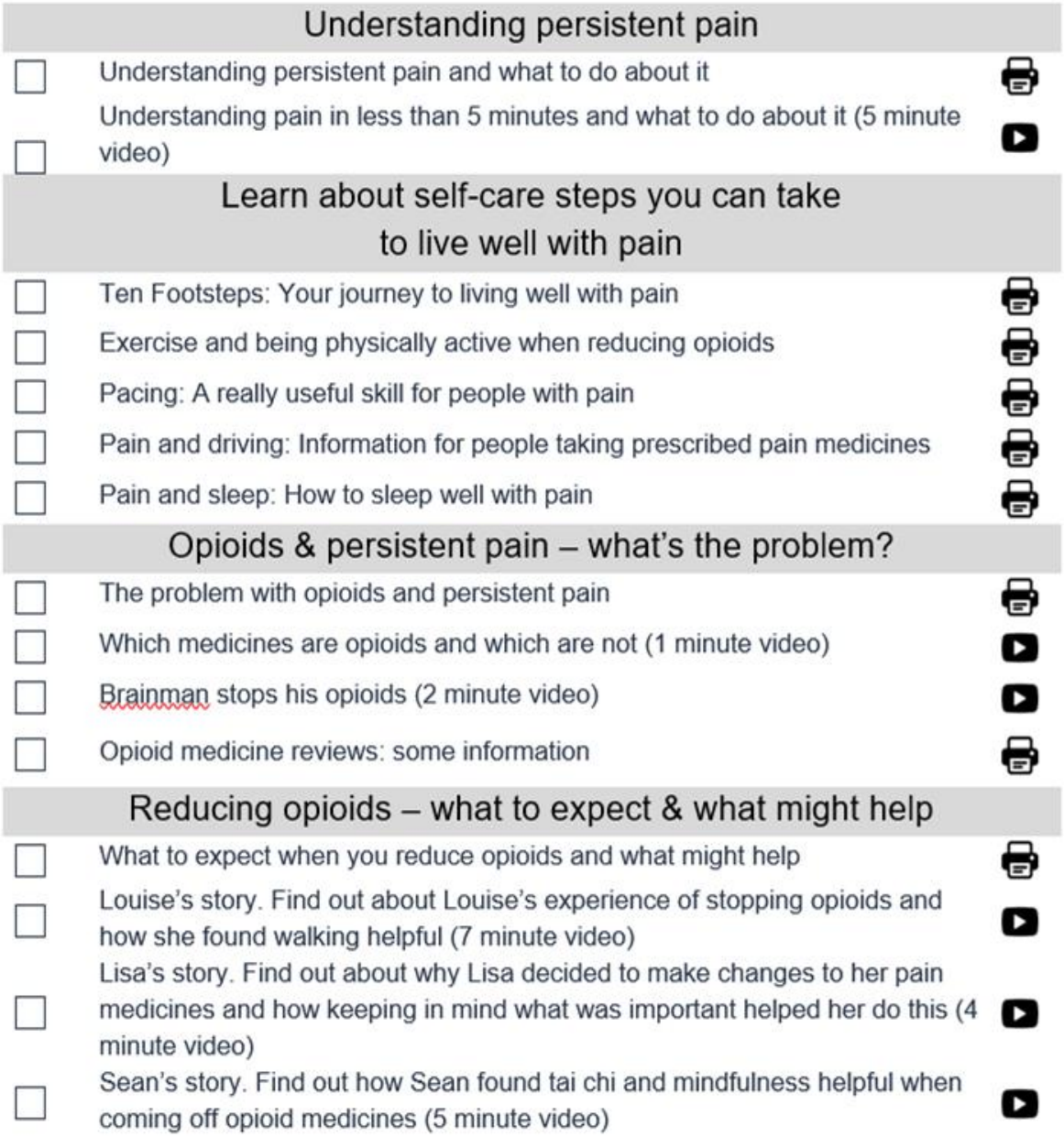
Your next appointment is on Friday 11 November 2021 at 09:00.

If you need to contact me, please call 01782 000111.
I will get back to you as soon as I can.

3.3.4 Self-care information

The self-care information we have selected for PROMPPT is organised into four groups, two of which are more broadly about pain and pain self-care and two that focus on opioids (see figure 3.5). The links to the self-care information are available in **training manual section 4.5, *Patient information resources*** and an interactive version of the self-care information as shown in figure 3.5 can be found in the PROMPPT Resource Library in the E-learning package.

Figure 3.5 PROMPPT self-care information



The first group of opioid resources explain some of the problems of taking regular opioids and why it's important to have regular reviews. These may be of some interest to patients who are uncertain, or not ready to make changes to their medicines.

The second group of opioid resources are about what to expect when reducing opioids and what might help. Patient groups told us that other people's experiences with pain and opioids are really important. So in this last group of resources, there are links to three short clips with Lisa, Louise and Sean's stories of living with pain whilst taking regular opioid medicines and then their own shift towards self-care for their conditions.

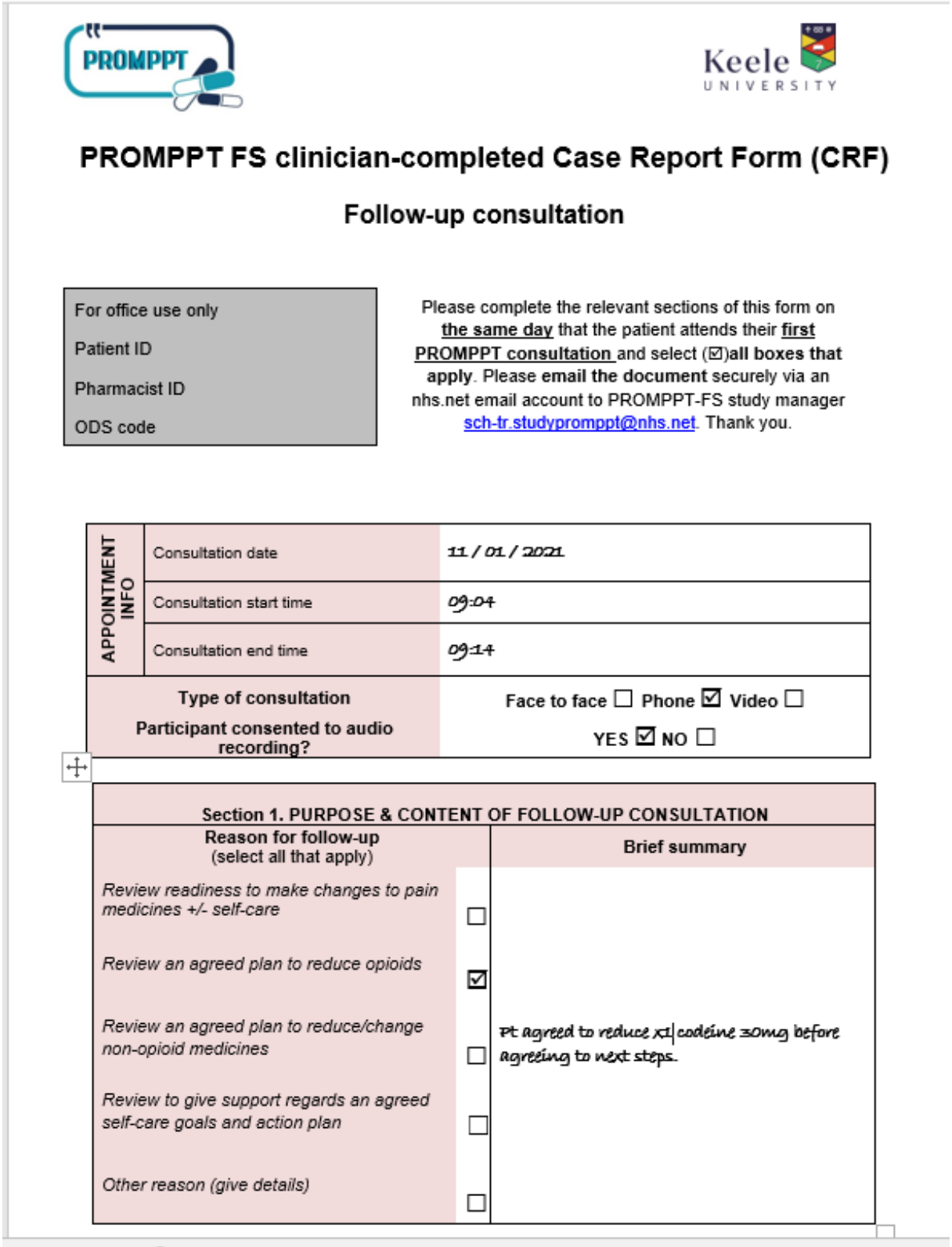
Our suggestion is to tick a few of those that you think will be most useful to the patient, but to encourage them to have a look at the website and all those that may catch their eye.

3.3.5 Follow-up CRF

The grey box "For office use only" on the Follow-up CRF will auto-populate in the same way as outlined for the First Assessment CRF. Please complete the requested information about the appointment and then the consultation, see the example below for your reference.

On the same day as your consultation, please email the completed CRF to the study manager (sch-tr.studypromppt@nhs.net).

Figure 3.6 PROMPPT follow-up Case Report Form



PROMPPT

Keele UNIVERSITY

PROMPPT FS clinician-completed Case Report Form (CRF)

Follow-up consultation

For office use only
Patient ID
Pharmacist ID
ODS code

Please complete the relevant sections of this form on **the same day** that the patient attends their **first PROMPPT consultation** and select (☑)**all boxes that apply**. Please **email the document** securely via an nhs.net email account to PROMPPT-FS study manager sch-tr.studypromppt@nhs.net. Thank you.

APPOINTMENT INFO	Consultation date	11 / 01 / 2021
	Consultation start time	09:04
	Consultation end time	09:14
Type of consultation		Face to face ☐ Phone ☑ Video ☐
Participant consented to audio recording?		YES ☑ NO ☐

Section 1. PURPOSE & CONTENT OF FOLLOW-UP CONSULTATION		
Reason for follow-up (select all that apply)		**Brief summary**
Review readiness to make changes to pain medicines +/- self-care	☐	
Review an agreed plan to reduce opioids	☑	
Review an agreed plan to reduce/change non-opioid medicines	☐	Pt agreed to reduce x1 codeine 30mg before agreeing to next steps.
Review to give support regards an agreed self-care goals and action plan	☐	
Other reason (give details)	☐	

Section 2. RESPONSE TO CHANGES IN PAIN MEDICINES	
*If **no** existing plan to reduce medicines in place go straight to section 3.*	
Patient has existing plan to reduce/taper opioids ☑	**Patient has existing plan to make changes to non-opioid pain medicines** ☐
Effect of making changes (select all that apply & add summary where relevant)	**Brief summary**
Pain is less ☐ same ☑ worse ☐ *Activity (functioning) is* less ☐ same ☑ worse ☐ *Adverse effects (side-effects)* less ☐ same ☑ worse ☐ *Withdrawal symptoms* none ☑ mild ☐ severe ☐	Pt happy to continue with plan to make changes every 2-weeks.

Section 3. CHANGES TO MANAGEMENT PLAN		
Changes as a result of <u>this</u> follow-up (select all that apply & add summary where relevant)		**Brief summary**
Agreed to a new opioid reduction /tapering plan	☑	As above, also discussed getting more active- patient to phone local walking group to see about walks for beginners.
Agreed new changes to non-opioid pain medicines	☐	
Collaboration required with GP	☐	
Other (e.g. other collaboration / signposting / referral)	☐	
Arrangements for further contact discussed	☑	No change
Follow-up appointment scheduled	☑	Review in 4/52 before next repeat prescription issued.

<u>On the same day</u> that this CRF is completed, please email the document securely via an nhs.net email account to PROMPPT-FS study manager

sch-tr.studypromppt@nhs.net

3.4 GP collaboration

(See also: E-learning course- PROMPPT Pain Management Skills, GP collaboration)

This training manual covers the PROMPPT approach to deliver pain management reviews and some of the underlying theory that supports its implementation. Consultations about pain management often involve clinical complexity and there may be times when the manual may not be sufficient to encompass the presenting and emerging clinical scenario. Whilst your specific role is to deliver the PROMPPT intervention, you may find new challenges emerge as your clinical relationship develops and you may need to seek advice from one of the practice general practitioners (GPs).

GPs and practice staff will all have had some training in the aims and terminologies of PROMPPT. They will be motivated to support you to deliver the PROMPPT intervention and will be approachable in circumstances where you need to collaborate.

As already highlighted, it is impossible to list all conditions and circumstances when collaboration should be sought, and this will also depend on the individual and your own experience and expertise.

3.4.1 Consider the patient's history

Is there anything in the clinical history that raises concerns about an individual patient?

Here is a framework when considering seeking GP advice that may be useful:

Concerns about pain history

Persistent pain often varies in intensity and sometimes location. It is common for patients on opioids for persistent pain to report gradual worsening of their pain over time and their pain may also flare-up from time to time. Sometimes the reason for this may be apparent and often it is not. This is the natural course of persistent pain.

Discuss with a GP when patient reports persistent new pain and/or pain-related symptoms that haven't been discussed before. Pain-related symptoms that would be important to discuss with a GP include:

- pain-related breathlessness, nausea, sweating
- new history of pain at night

Concerns about general health

Discuss with a GP when patients:

- don't look "well" (pale, very frail) without good cause that has/is not being addressed
- present with weight loss for no good reason, night sweats, fatigue

Concerns about mental health

We outlined how to assess risk in patients with low mood in **training manual section 2.7.1, *Assessing risk in patients who are low in mood***. In this section we recap on this risk assessment with the focus on when to seek advice and support from the GP. There are other instances where you may need to discuss your patient with a GP and these include:

- New onset or worsening anxiety/ depression
- Evidence of self-neglect
- Visual evidence of recent self-harm or an admission of recent self-harm
- Hallucinations (hearing or seeing things that aren't there), delusions (fixed, false or irrational beliefs, despite being confronted by the rational facts), excessive paranoia or an apparent detachment from reality

If a patient reveals any of the above, consider a discussion with the GP. If a patient reveals there is a current risk of suicide, make a plan to discuss their case with the GP. The urgency of this discussion will depend on the perceived risk:

- **Immediate risk (patient reveals specific plan and intent to end life)**
    - **Stop work and speak to GP on the same day**
- **Moderate risk (frequent thoughts that are not easily dismissed, no immediate plan, intent could increase if circumstances change)**
    - **Speak to GP about current and future risk (same day) and/or ask patient to make urgent appointment with GP**
- **Low risk (fleeting suicidal thoughts, no intent, no plan)**
    - **Discuss with GP at routine catch-up (eg MDT) and/or ask for patient to make a routine appointment with GP**

Concerns about social history

- Is the patient drinking alcohol and has this increased to harmful levels (>14 units / week for adults) following a PROMPPT pain review and a change in their opioid medicines?
- Any other substance misuse that needs addressing?

3.4.2 Consider the outcome following a PROMPPT consultation

Concerns about new medicine prescribing

Consider discussing with a GP:

- if you feel there is scope to prescribe a new non-opioid analgesic and the patient wishes to try this option
- if the patient has changed, started or stopped other medicines that will potentially impact on an opioid reduction:
    - increased alternative analgesic use (NSAIDs, over-the-counter opioids)

- change in antidepressant dosing and type
- addition of sedative medications (e.g. benzodiazepines), gabapentinoids or amitriptyline

Concerns about opioid addiction

As highlighted earlier in this manual, most patients taking opioids for persistent pain are not addicted to opioids. Physical dependence does not mean that patients are addicted. However a small proportion of patients do develop behaviour that is consistent with opioid addiction **(please refer to training manual sections 1.2.3, *Effectiveness and risks of long-term opioid therapy for persistent pain*.**

If following your assessment, you feel there is evidence that raises the possibility of opioid misuse and addiction this warrants discussion with the GP, especially if the patient has indicated that they do not feel ready to consider reducing.

Concerns about prescribing safety

Discuss you concerns with a GP if:

- You encounter patients who are not willing or not ready to consider reducing opioids, who you feel are at risk from unsafe prescribing, for example:
    - high dose opioids
    - co-prescription of opioids with other sedating / potentially dependence forming medicines such as benzodiazepines and gabapentinoids

Non-pharmacological pain management

Discuss with a GP:

- if you need advice on the choice of alternative (non-pharmacological) strategy for coping with pain in this particular patient
- if you wish to consider referral for further help with pain management

Finally, remember to act on your instinct. If you feel you need to ask for advice or seek collaboration, then it is absolutely appropriate to do so.

3.4.3 How to seek advice / collaboration

The level of collaboration will depend on the urgency, significance and severity of the problem; trust your instincts. There may be circumstances where collaboration will be needed at the time of review (for example if very unwell or displaying significant suicidal intent).

- Asking patients to make an ‘urgent’ GP appointment (within 2 weeks) would be appropriate for concerns about new or worsening health problems
- A routine GP appointment would be appropriate for concerns over long-standing symptoms or problems related to opioid reduction

When advising patients to make GP appointments, it is good practice to communicate this to the GP team through the means established at your practice, which may involve a face to face discussion, or a message/email through the internal practice messaging system.

Each practice will provide support for you when needed. However, all GP practices work in different ways and will have unique models of care and so it is important to establish with the practice you are based in how they would prefer you to collaborate with them. Some practices may want to establish a formal PROMPPT review rota, where there is an allocated GP to discuss PROMPPT concerns during each session, whilst others may want to take a more ad-hoc approach.

To facilitate optimal collaboration within your practice, we suggest you:

- Find out who the lead PROMPPT GP and PROMPPT practice champion are (they may be the same person) and arrange to meet them
- Establish how the practice would like to approach collaboration when clinical input is needed
- Talk to the lead PROMPPT GP about the best way for you both to collaborate with each other
- Speak with the practice manager to find out how front of house are getting involved with PROMPPT

Some practices may have regular shared learning and team meetings for generic skills and clinical training. These meetings are often valuable opportunities for the practice to learn and share experiences, develop skills and build and establish working relationships that will facilitate the aims and objectives of the PROMPPT review.

3.5 Next steps

(See also: E-learning course- PROMPPT Pain Management Skills, Next steps (follow-up, sign-posting & referrals)

3.5.1 Follow-up

Follow-up will be arranged according to clinical need. Patients will also be provided with a clear plan for how to contact the clinical pharmacist between appointments if needed. Follow-up appointments are anticipated to be shorter in duration (no longer than 15 minutes) than the first PROMPPT assessment.

Follow-up appointments could be arranged for a number of reasons. The most likely reasons to see a patient again will be to:

- Review readiness to make changes to pain medicines +/- self-care
- Review an agreed plan to reduce opioids
- Review an agreed plan to reduce/change non-opioid medicines
- Review to give support regards agreed self-care goals and action plan

There may be other reasons and this will be important for the research team to find out.

Not all patients you will follow-up will have an existing plan to reduce or make changes to the medicines they regularly take for pain. For those patients, a follow-up appointment is an opportunity to review the following:

- Any overall change in pain (remembering that pain does tend to come and go over time)
- Any overall change in the level of engagement in day to day activities and the things that are important to the individual patient
- Any change in the adverse effects of the opioids and/or non-opioid pain medicines
- Whether the patient experienced any withdrawal symptoms and to what extent and duration any symptoms interfered with their day-to-day living

Further follow-up appointments can then be arranged as you and the patient feel necessary and appropriate.

3.5.2 Signposting & Referral

You may wish to discuss cases with your GP if you are considering referrals to other services. This section outlines some of the services that are often useful for patients consulting with persistent pain.

Guidance for referring to pain services

In some patients pain-related distress and suffering due to the wider aspects of pain may get in the way of day-to-day life and in some it may be overwhelming. In these often complex cases, an interdisciplinary pain rehabilitation approach may help the patients to move forwards. Patients benefit the most from this type of approach once they have completed all active investigations and treatments (such as scans, injections and surgery) for their pain. Similarly, it is important that the expectation of pain services is understood by patients prior to referral and you may wish to explain to patients that pain services aim is to support patients to adjust to living with pain rather than reducing or controlling pain.

Guidance for referring to physiotherapy services

In some cases, patients may report problems in doing some of their normal activities of daily living because of pain, for example, reduced mobility or problems dressing. If patients are looking to address any related reduction in function, they may benefit from an assessment and treatment under physiotherapy services.

In the PROMPPT population the aim of physiotherapy may be more to improve function rather than to reduce pain. You may wish to explain this to patients before agreeing to a

referral (for example *"Physiotherapy may help you to become stronger which will make it easier for you to [walk/drive/work]").*

Guidance for referring to local mental health support services

Consider a referral to your local mental health services when patients with low mood or anxiety are looking for practical support and talking therapies when there is no immediate risk.

3.6 Pharmacist self-care

(See also: E-learning course- PROMPPT Pain Management Skills, Some thoughts and tips on your own self-care)

There is a lot of information in this training manual and we hope that it will prepare you well for undertaking PROMPPT consultations. However, some of it may be new and you may not have previously used some of the skills needed for PROMPPT, this can make the task ahead feel daunting.

As we've discussed, it's important that PROMPPT is delivered with a whole practice approach, which we hope means that GPs at your practice are available to talk through difficulties you may be facing. Remember you can also contact the clinical champions, who are experienced clinical pharmacist, acting in a mentorship role within PROMPPT.
Support is available to you whilst you are taking part in PROMPPT but it is also important to think about your own self-care, now and during your day to day work.

Like teaching self-management to patients, teaching self-care to healthcare professionals can be difficult. Especially when they want to do the best for patients, sometimes at a cost to their own mental health and wellbeing. Self-care is often a case of trial and error, findings things that work for you and allow you to cope with the stresses and strains that are thrown at you. However, there are lots of resources available to help you find what works.
You're likely not new to feeling some pressure and emotions from your work life and have probably already got self-care strategies in place. Have a think about the techniques you use, some of them might be the very same things we suggest to patients!
Some ideas:

- Exercise and being active
- Meditation and mindfulness
- Relaxing activities such as reading, craft, art or cooking
- Doing things you enjoy
- Socialising and taking your mind away from work
- Talking to colleagues about difficult scenarios
- Talking to those close to you about your emotions

Once you've had a think about the ways you already look after your own wellbeing, complete the E-learning module, it has some videos to watch, works through a case study and signposts you to further resources.

4. PROMPPT Resource Library

The following pages show copies of the study documentation, they are also available to download from the E-learning package: PROMPPT Resource Library.

4.1 Patient Invitation Letter

GP HEADED PAPER

MPFT NHS
Midlands Partnership
NHS Foundation Trust
A Keele University Teaching Trust

«Title» «Forename» «Surname»
«Address Line 1»
«Address Line 2»
«Address Line 3»
«Postcode»

Our ref: «Study ID»
Date: «Day» «Month» «Year»

Dear «Title» «Surname»,

Our practice is working with Keele University, on a research study called PROMPPT. PROMPPT is looking at a new way of reviewing how patients, like you, are managing their pain.

We would like to invite you to arrange a pain review to look at how you are managing your long-term pain. Your appointment will be with [first name, last name], the practice clinical pharmacist.

[First name] works in our practice as part of the healthcare team as a clinical pharmacist. [He/she/they] [has/have] done specialist training to provide expert advice and support on medicines to patients, doctors and other healthcare professionals. [He/she/they] will have access to your medical records, just like your GP or the practice nurse.

There will be **plenty of time for you to talk** to [first name] about how you manage your pain, your first appointment will be for **30 minutes**. [He/she/they] may be able to help you to make changes to your life to help you manage your pain, if needed.

You have been invited for this review because we have noticed that we have prescribed you opioid painkillers regularly for 6-months, or more. Opioid medicines are commonly prescribed to patients with pain but they are not always of clear benefit and can cause some bothersome side-effects. [First name] will talk to you about how all your pain medicines, are working for you and any problems, or concerns you might have.

Your appointment will be an opportunity to talk about how pain affects your life. If you and [First name] think your medicines are not clearly helping, and/or are causing unwanted effects they may suggest that you try making changes to your opioid medicines.

We hope that you will take up this opportunity to discuss your pain management with our practice clinical pharmacist. If you are interested, **please contact the practice on [practice telephone number] at your earliest convenience to book your appointment with our practice clinical pharmacist.**

Enclosed is a form (called the Pain Concerns Form) to help you and [first name] talk about concerns that you may have about your pain and the medicines that you use for your pain. It will help you focus on the things that are most important to you during your appointment.

Please complete the enclosed Pain Concerns Form and bring it to your appointment with the practice clinical pharmacist.

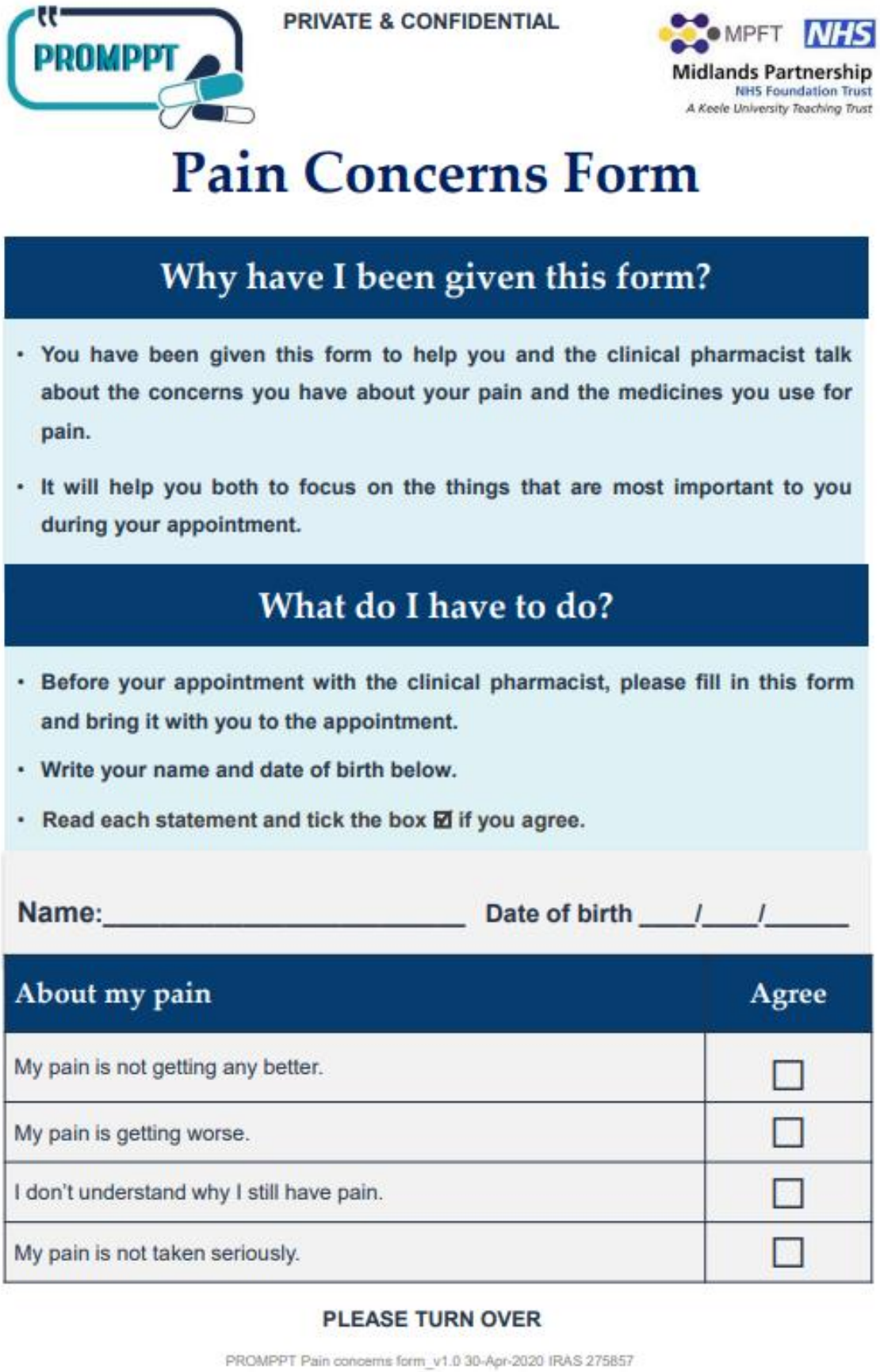
If you have any questions or would like to know more about this appointment, please contact the practice using on **[practice telephone number].**

Yours sincerely,

[NAMED GP]
Enc: PROMPPT Pain Concerns form

PROMPPT Patient invitation to pain review v1.1_04-June-2020 IRAS: 275857

4.2 Pain Concerns Form



PRIVATE & CONFIDENTIAL

MPFT NHS
Midlands Partnership
NHS Foundation Trust
A Keele University Teaching Trust

Pain Concerns Form

Why have I been given this form?

- You have been given this form to help you and the clinical pharmacist talk about the concerns you have about your pain and the medicines you use for pain.
- It will help you both to focus on the things that are most important to you during your appointment.

What do I have to do?

- Before your appointment with the clinical pharmacist, please fill in this form and bring it with you to the appointment.
- Write your name and date of birth below.
- Read each statement and tick the box ☑ if you agree.

Name:_____ **Date of birth** ____/____/_____

About my pain	Agree
My pain is not getting any better.	☐
My pain is getting worse.	☐
I don't understand why I still have pain.	☐
My pain is not taken seriously.	☐

PLEASE TURN OVER

PROMPPT Pain concerns form_v1.0 30-Apr-2020 IRAS 275857

PRIVATE & CONFIDENTIAL

Read each statement and tick the box ☑ if you agree.

Because of my pain…	Agree
I can't do my usual day-to-day activities e.g. housework, hobbies and social activities.	☐
I can't continue in or return to work.	☐
My pain stops me getting a good nights sleep.	☐
I feel stressed, *or* I feel anxious.	☐
My mood is low.	☐
I feel frustrated or embarrassed that I can't do things.	☐
I see my family and friends less than I used to.	☐
I feel lonely and isolated.	☐
I want to talk about the impact of my pain at my appointment	☐

Regarding the medicines I take for pain…	Agree
I am concerned that these medicines do not help my pain enough.	☐
I am concerned about how many medicines I take for pain.	☐
I am concerned about the combination of medicines I take.	☐
I am concerned about the short-term and/or long-term effects of my pain medicines.	☐
I am concerned that my pain medicines will be stopped.	☐

Other concerns relating to my pain or my pain management are...

THANK YOU FOR COMPLETING THIS FORM

PLEASE BRING IT ALONG TO YOUR APPOINTMENT WITH THE CLINICAL PHARMACIST

4.3 Pain review plan & self-care information

Pain Review Plan & Self-care Information

All the resources suggested in this leaflet are available online via the PROMPPT website. To access the resources, you can either:

Scan the QR code below using the camera on your smartphone

or

Click here or enter the following link into your internet browser

https://www.promppt.co.uk/protected/resources.html

Your PROMPPT username is: user
Your PROMPPT password is: info2023

SCAN ME

Pain review plan

Thank you for coming to see me, here is a brief reminder of the pain management plan we agreed for you:

We have agreed to have another appointment together **YES** ☒ **NO** ☐

Your next appointment is on day date month at hh:mm.

If you need to contact me, please call xxxxx xxxxxx.
I will get back to you as soon as I can.

Self-care information

Based on our discussion, I have ticked ☑ the areas I think are most important to you to find out more about.

Please have a look at any of the information that is of interest to you. You may also like to share this information with family and friends to help them understand so that they can support you.

All the information is available online. You can find it by following the instructions on the front page of this leaflet and entering the username and password provided.

Some of the information resources listed are written leaflets for you to read, some are websites and some are videos you can watch.

If you have told me that you do not have access to the internet and/or prefer printed information, I will provide you with paper copies of the information leaflets.

	Understanding persistent pain	
☐	Understanding persistent pain and what to do about it	
☐	Understanding pain in less than 5 minutes and what to do about it (5 minute video)	
	Learn about self-care steps you can take to live well with pain	
☐	Ten Footsteps: Your journey to living well with pain	
☐	Exercise and being physically active when reducing opioids	
☐	Pacing: A really useful skill for people with pain	
☐	Pain and driving: Information for people taking prescribed pain medicines	
☐	Pain and sleep: How to sleep well with pain	
	Opioids & persistent pain – what's the problem?	
☐	The problem with opioids and persistent pain	
☐	Which medicines are opioids and which are not (1 minute video)	
☐	Brainman stops his opioids (2 minute video)	
☐	Opioid medicine reviews: some information	
	Reducing opioids – what to expect & what might help	
☐	What to expect when you reduce opioids and what might help	
☐	Louise's story. Find out about Louise's experience of stopping opioids and how she found walking helpful (7 minute video)	
☐	Lisa's story. Find out about why Lisa decided to make changes to her pain medicines and how keeping in mind what was important helped her do this (4 minute video)	
☐	Sean's story. Find out how Sean found tai chi and mindfulness helpful when coming off opioid medicines (5 minute video)	

4.4 Case report forms

Clinician completed first assessment case report form

PROMPPT FS First Assessment Case Report Form (CRF)

For office use only
Patient ID
Pharmacist ID
ODS code

Please complete this form (CRF) on **the same day** that the patient attends their **first PROMPPT consultation.** Select all the boxes ☑ that apply and write a brief summary where relevant . Please **email the document** securely via an nhs.net email account to PROMPPT-FS study manager sch-tr.studypromppt@nhs.net. Thank you.

APPOINTMENT INFO	Consultation date	.. / .. / ..
	Consultation start time	hh:mm
	Consultation end time	hh:mm
Type of consultation		**Face to face** ☐ **Phone** ☐ **Video** ☐
Participant consented to audio recording?		**YES** ☐ **NO** ☐

COMPLETED DURING FIRST ASSESSMENT (CHECK BOX)		BRIEF SUMMARY
Current opioid use (select one of the following)		
The patient regularly takes the full dose(s) of prescribed opioids	☐	
Patient takes the opioids as required according to their prescription	☐	
Patient's opioid use is not as prescribed (give details)	☐	

COMPLETED DURING FIRST ASSESSMENT (check box)		BRIEF SUMMARY
Invited patient to tell story about pain	☐	
Used Pain Concerns form to explore persistent pain more widely	☐	
Explored effects of opioids (select all that apply & add summary where relevant)		
Analgesia (pain relief)	☐	
Activity (functional improvement)	☐	
Adverse effects (side-effects, complications)	☐	
Aberrant behaviour (non-compliance, misuse)	☐	
Assessed patient perspective on changing opioids (select one of the following & add summary where relevant)		
Not ready	☐	
Ambivalent	☐	
Ready	☐	
Discussed options for self-care	☐	
Management plan (select all that apply & add summary where relevant)		
Agreed an opioid reduction /tapering plan	☐	
Agreed changes to other pain medicines	☐	
Collaboration required with GP	☐	
Collaboration required with others in members of practice MDT	☐	
Signposting / referral (select any that apply & add summary where relevant)		
Mental health support services	☐	
Physiotherapy	☐	
Pain services	☐	
Other (give details)	☐	
Patient review plan completed	☐	
Patient self-care information completed	☐	
Further contact arrangements discussed	☐	
Follow-up appointment scheduled	☐	

On the **same day** as the consultation, please email the document securely via an nhs.net email account to PROMPPT-FS study manager: sch-tr.studypromppt@nhs.net

Clinician completed follow-up case report form

PROMPPT FS clinician-completed Case Report Form (CRF)

Follow-up consultation

For office use only
Patient ID
Pharmacist ID
ODS code

Please complete the relevant sections of this form on **the same day** that the patient attends their **first PROMPPT consultation** and select (☑)**all boxes that apply**. Please **email the document** securely via an nhs.net email account to PROMPPT-FS study manager sch-tr.studypromppt@nhs.net. Thank you.

APPOINTMENT INFO	Consultation date	.. / .. / ..
	Consultation start time	hh:mm
	Consultation end time	hh:mm
Type of consultation		**Face to face ☐ Phone ☐ Video ☐**
Participant consented to audio recording?		**YES ☐ NO ☐**

Section 1. PURPOSE & CONTENT OF FOLLOW-UP CONSULTATION		
Reason for follow-up (select all that apply)		**Brief summary**
Review readiness to make changes to pain medicines +/- self-care	☐	
Review an agreed plan to reduce opioids	☐	
Review an agreed plan to reduce/change non-opioid medicines	☐	
Review to give support regards an agreed self-care goals and action plan	☐	
Other reason (give details)	☐	

Section 2. RESPONSE TO CHANGES IN PAIN MEDICINES	
*If **no** existing plan to reduce medicines in place go straight to section 3.*	
Patient has existing plan to reduce/taper opioids ☐	**Patient has existing plan to make changes to non-opioid pain medicines** ☐
Effect of making changes (select all that apply & add summary where relevant)	**Brief summary**
Pain is less ☐ same ☐ worse ☐ *Activity (functioning) is* less ☐ same ☐ worse ☐ *Adverse effects (side-effects)* less ☐ same ☐ worse ☐ *Withdrawal symptoms* none ☐ mild ☐ severe ☐	
Section 3. CHANGES TO MANAGEMENT PLAN	
Changes as a result of <u>this</u> follow-up (select all that apply & add summary where relevant)	**Brief summary**
Agreed to a new opioid reduction /tapering plan ☐ *Agreed new changes to non-opioid pain medicines* ☐ *Collaboration required with GP* ☐ *Other (e.g. other collaboration / signposting / referral)* ☐	
Arrangements for further contact discussed ☐	
Follow-up appointment scheduled ☐	

<u>On the same day</u> that this CRF is completed, please email the document securely via an nhs.net email account to PROMPPT-FS study manager

sch-tr.studypromppt@nhs.net

4.5 Patient information resources

Below are links to patient resources you may want to familiarise yourself with, you may have already seen some of the resources from links throughout the training manual and they are also available in the E-Learning platform: PROMPPT Resource Library.

Understanding persistent pain

- Understanding persistent pain and what to do about it
- Understanding pain in less than 5 minutes (video)

Learn about self-care

- Ten footsteps
- Exercise and being physically active when reducing opioids
- Pacing
- Pain and driving
- Pain and sleep

Opioids and persistent pain

- The problem with opioids and persistent pain
- Which medicines are opioids and which are not (video)
- Brainman stops his opioids (video)
- Opioid medicine reviews

Reducing opioids

- What to expect when you reduce opioids
- Louise's story
- Lisa's story
- Sean's story

4.6 Additional learning materials

Below are links to additional reading you may find helpful, you may have already seen some of the resources from links throughout the training manual and they are also available in the E-Learning platform: PROMPPT Resource Library.

- Shared decision making: a model for clinical practice
- A three-talk model for shared decision making: multistage consultation process
- When is a shared decision not (quite) a shared decision? Negotiating preference in a general practice encounter
- Management of the difficult patient
- Communicating with patients from all backgrounds
- Motivational interviewing
- Opioid equianalgesic calculator developed by the Faculty of Pain Medicine, Australian and New Zealand College of Anaesthetists (FPM ANZCA), to calculate the total daily morphine equivalent daily dose (MED).
- PHE advice on pregabalin and gabapentin
- Benzodiazepine and Z-drug deprescribing algorithm
- NICE Guideline on Depression in Adults

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